



## Deklaracja producenta

w związku z rozporządzeniem (UE) 2023/607, zmieniającym rozporządzenia (UE) 2017/745 i (UE) 2017/746 w zakresie przepisów przejściowych dotyczących niektórych wyrobów medycznych oraz wyrobów medycznych do diagnostyki in vitro, w szczególności w odniesieniu do

- ważności certyfikatów wystawionych na mocy dyrektywy Rady 90/385/EWG w sprawie aktywnych wyrobów medycznych do implantacji (AIMDD - Active Implantable Medical Devices) lub dyrektywy Rady 93/42/EWG w sprawie wyrobów medycznych (MDD - Medical Device Directive) (certyfikatów wystawionych wg dyrektywy medycznej) *i/lub*<sup>1</sup>
- zgodności wyrobów i naszej firmy, jako ich producenta z warunkami dalszego wprowadzania tych wyrobów do obrotu i oddawania do użytku

Nazwa producenta	<b>Ethicon Endo-Surgery, LLC</b>
Adres producenta i dane kontaktowe	<b>475 Calle C Guaynabo, Portoryko 00969 USA</b>  <b>Kontakt: Kim Shoemaker E-mail: kshoema1@its.jnj.com</b>
Niepowtarzalny numer rejestracyjny (SRN) (jeśli jest dostępny)	<b>US-MF-000013107</b>

Nazwa upoważnionego przedstawiciela (jeśli dotyczy)	<b>Johnson &amp; Johnson Medical GmbH</b>
Adres i dane kontaktowe upoważnionego przedstawiciela	<b>Robert-Koch-Str. 1 22851 Norderstedt Niemcy</b>  <b>Kontakt: Fabian Spaenig E-mail: jjmear@its.jnj.com</b>
Numer rejestracyjny (SRN) producenta (jeśli jest dostępny)	<b>DE-AR-000007712</b>

<sup>1</sup> Pierwszy warunek nie ma zastosowania dla wyrobów, dla których procedura oceny zgodności według dyrektywy MDD nie wymagała zaangażowania jednostki notyfikowanej, dla których deklaracja zgodności została sporządzona przed dniem 26 maja 2021 r. i dla których ocena zgodności według niniejszego rozporządzenia wymaga zaangażowania jednostki notyfikowanej.



Nazwa jednostki notyfikowanej (jeśli dotyczy)	TÜV SÜD Product Service GmbH
Numer jednostki notyfikowanej (jeśli dotyczy)	0123
Numer(y) certyfikatu(-ów) wg dyrektywy do którego odnosi się niniejsze potwierdzenie (jeżeli dotyczy)	<input type="checkbox"/> <b>Zobacz załączony wykaz</b>
Pierwotna data ważności wskazana na ww. certyfikacie wg dyrektywy przed przedłużeniem ważności (jeśli ten warunek obowiązuje)	<input type="checkbox"/> <b>Zobacz załączony wykaz</b>
Data wygaśnięcia przedłużonego okresu ważności/okresu przejściowego	<input type="checkbox"/> <b>Zobacz załączony wykaz</b>

Jako producent, firma nasza oświadcza na swoją wyłączną odpowiedzialność:

- w odniesieniu do wyżej wymienionego **certyfikatu dyrektywy** (lub patrz załączony wykaz, w przypadku wielu certyfikatów) spełnione są warunki prawnego przedłużenia ważności zgodnie z wymogami art. 120 ust. 2 rozporządzenia MDR *i/lub*<sup>2</sup>
- **wyroby** wymienione w załączonym wykazie i my jako ich producent spełniamy warunki wymienione w art. 120 ust. 3c rozporządzenia MDR dotyczące dalszego wprowadzania do obrotu i oddawania do użytku,

mianowicie poprzez spełnienie następujących warunków:

➤ **certyfikat(y) wg dyrektywy – jeśli występuje(a) – jak podano powyżej lub w załączonym wykazie**

- certyfikat(y), wystawione wg ww. dyrektywy, obejmujące wymienione wyroby) został(y) wystawione po 25 maja 2017 r., były ważne do 26 maja 2021 r., nie zostały po tym terminie wycofane

*Należy wybrać właściwe stwierdzenie:*

☐ Ważność wygasła *przed* 20 marca 2023:

- ☐ Przed pierwotną datą wygaśnięcia ważności, wskazaną w certyfikatach wystawionych wg ww. dyrektywy, nasza firma i jednostka notyfikowana podpisały pisemną umowę(-y) zgodnie z punktem 4.3, podakapit drugi załącznika VII do niniejszego rozporządzenia w sprawie oceny(-y) zgodności w odniesieniu do wyrobu(ów) objętego(-ych) certyfikatem(-ami), którego(-ych) ważność) wygasł(-ych) lub w odniesieniu do wyrobu(-ów) przeznaczonego(-ych) do zastąpienia tego(-ych) wyrobu(-ów), lub

<sup>2</sup> Pierwszy warunek nie ma zastosowania dla wyrobów, dla których procedura oceny zgodności według dyrektywy MDD nie wymagała zaangażowania jednostki notyfikowanej, dla których deklaracja zgodności została sporządzona przed dniem 26 maja 2021 r. i dla których ocena zgodności według niniejszego rozporządzenia wymaga zaangażowania jednostki notyfikowanej.

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- ☐ właściwy organ wyraził zgodę na odstępstwa od obowiązującej procedury oceny zgodności zgodnie z art. 59 ust. 1 rozporządzenia MDR,
- ☐ właściwy organ zażądał od producenta, zgodnie z art. 97 ust. 1 rozporządzenia MDR, przeprowadzenia stosownej procedury oceny zgodności (żądanie to może zostać przedłożone na życzenie)

*Należy wybrać jedno z poniższych stwierdzeń tylko w przypadku, kiedy właściwy organ przyznał odstępstwo zgodnie z art. 59 ust. 1 lub wymóg zgodnie z art. 97 ust. 1:*

- ☐ Formalny(e)wniosek (wnioski) do jednostki notyfikowanej, zgodnie z punktem 4.3 podakapit pierwszy załącznika VII do rozporządzenia MDR o ocenę zgodności został (zostały) lub zostanie (zostaną) złożony (złożone) przez naszą firmę do jednostki notyfikowanej nie później niż 26 maja 2024 r. dla wyrobu (wyrobów) wymienionego (wymienionych) w załączonym wykazie lub jego (ich) zamiennika (zamienników), a podpisana pisemna umowa (podpisane pisemne umowy) została (zostaną) zawarta (zawarte) zgodnie z punktem 4.3 podakapit drugi załącznika VII do rozporządzenia MDR przed 26 września 2024 r.
- ☐ Firma nasza nie zamierza składać wniosku o ocenę zgodności do 26 maja 2024 r., dlatego okres przejściowy zakończy się 26 maja 2024 r.

☒ Ważność wygasa/wygasa po 20 marca 2023:

*Należy wybrać odpowiednie stwierdzenie:*

- ☒ Formalny(e) wniosek (wnioski) do jednostki notyfikowanej, zgodnie z punktem 4.3 podakapit pierwszy załącznika VII do rozporządzenia MDR o ocenę zgodności został (zostały) lub zostanie (zostaną) złożony (złożone) przez naszą firmę do jednostki notyfikowanej nie później niż 26 maja 2024 r. dla wyrobu (wyrobów) wymienionego (wymienionych) w załączonym wykazie lub jego (ich) zamiennika (zamienników), a podpisana pisemna umowa (podpisane pisemne umowy) została (zostaną) zawarta (zawarte) zgodnie z punktem 4.3 podakapit drugi Załącznika VII do rozporządzenia MDR przed 26 września 2024 r.
- ☐ Firma nasza nie zamierza składać wniosku o ocenę zgodności do 26 maja 2024 r., dlatego okres przejściowy zakończy się 26 maja 2024 r.

## ➤ Wyroby ulepszone

W przypadku wyrobów, dla których procedura oceny zgodności, zgodnie z dyrektywą MDD, nie wymagała zaangażowania jednostki notyfikowanej, dla których deklaracja zgodności została sporządzona przed dniem 26 maja 2021 r. i dla których procedura oceny zgodności zgodnie z niniejszym rozporządzeniem wymaga zaangażowania jednostki notyfikowanej:

*Należy wybrać właściwe stwierdzenie:*

- ☒ Formalny(e)wniosek (wnioski) do jednostki notyfikowanej, zgodnie z punktem 4.3 podakapit pierwszy załącznika VII do rozporządzenia MDR o ocenę zgodności został (zostały) lub zostanie (zostaną) złożony (złożone) przez naszą firmę do jednostki notyfikowanej nie później niż 26 maja 2024 r. dla wyrobu (wyrobów) wymienionego (wymienionych) w załączonym wykazie lub jego (ich)

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zamiennika (zamienników), a podpisana pisemna umowa (podpisane pisemne umowy) została (zostaną) zawarta (zawarte) zgodnie z punktem 4.3 podakapit drugi załącznika VII do rozporządzenia MDR przed 26 września 2024 r.

- ☐ Firma nasza nie zamierza składać wniosku o ocenę zgodności do 26 maja 2024 r., dlatego okres przejściowy zakończy się 26 maja 2024 r.

➤ **System zarządzania jakością (QMS - Quality Management System)**

Należy wybrać właściwe stwierdzenie:

- ☐ System QMS zgodnie z art. 10 ust. 9 rozporządzenia MDR zostanie wprowadzony najpóźniej do 26 maja 2024 r.
- ☐ Wprowadzony został system zarządzania jakością (QMS), zgodnie z art. 10 ust. 9 rozporządzenia MDR
- ☒ Jednostka notyfikowana wystawiła załączony certyfikat dla systemu zarządzania jakością (QMS) zgodnego z rozporządzeniem MDR.

➤ **Wyrób (wyroby) wymieniony(-e) w załączonym wykazie**

- Wyrób (wyroby) nadal jest (są) zgodny(e) z dyrektywą w sprawie wyrobów medycznych aktywnego osadzania (AIMDD) lub dyrektywą w sprawie wyrobów medycznych (MDD).
- Nie ma znaczących zmian w projekcie i przeznaczeniu.
- Wyrób (wyroby) nie stwarza(ją) niedopuszczalnego ryzyka dla zdrowia lub bezpieczeństwa pacjentów, użytkowników lub innych osób, ani dla innych aspektów ochrony zdrowia publicznego.

Podpisał w imieniu producenta:

SEKCJA PODPISÓW			
Miejsce wystawienia	Guaynabo, Portoryko		
Podpis	Electronically signed by: M KIMBERLY SHOEMAKER Reason: I am approving this document M KIMBERLY SHOEMAKER Date: Feb 14, 2024 13:50 EST	Data	Zobacz e-podpis
Nazwisko/stanowisko	Kim Shoemaker, Starszy Dyrektor ds. Regulacji kshoema1@its.jnj.com		

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<b>Podpis</b>	<i>Electronically signed by:</i> <b>MARJORIE MEDINA</b> <i>Reason: I am approving this document</i> <b>MARJORIE MEDINA</b> <i>Date: Feb 14, 2024 11:10 AST</i>	<b>Data</b>	Zobacz e-podpis
<b>Nazwisko/stanowisko</b>	Marjorie Medina, Senior Director Quality Source MD mmedina6@its.jnj.com Osoba w zakładzie producenta odpowiedzialna za zgodność z przepisami		
<b>HISTORIA ZMIAN</b>			
<b>Wersja</b>			
<b>A</b>	Wersja oryginalna (Windchill nr 501479326)		
<b>B</b>	Zmieniono w celu uwzględnienia dodatkowych kodów produktów (NSLX125S, NSLX137S, NSLX125C, NSLX137C, NSLX145C, HAR1120, HAR1136, HARHPBL, HARHPBLCN, HARHPGR, HARHPGRCN, NSLG2C35A, NSLG2C45A, NSLG2S35A, NSLG2S45A)** Uwaga: zmieniono historię wersji z wersji 0 na wersję A w celu wewnętrznego śledzenia dokumentacji. Dodano Windchill nr		



## Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*<sup>1</sup>
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	<b>Ethicon Endo-Surgery, LLC</b>
Manufacturer address and contact details	<b>475 Calle C Guaynabo, Puerto Rico 00969 USA</b>  <b>Contact: Kim Shoemaker Email: kshoema1@its.jnj.com</b>
Single Registration Number (SRN) (if available)	<b>US-MF-000013107</b>

Authorised Representative name (if applicable)	<b>Johnson &amp; Johnson Medical GmbH</b>
Authorised Representative address and contact details	<b>Robert-Koch-Str. 1 22851 Norderstedt Germany</b>  <b>Contact: Fabian Spaenig Email: jjmear@its.jnj.com</b>
Single Registration Number (SRN) (if available)	<b>DE-AR-000007712</b>

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<sup>1</sup> The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.



Notified body name (if applicable)	TÜV SÜD Product Service GmbH
Notified body number (if applicable)	0123
Directive Certificate number(s) to which this confirmation is made (if applicable)	<input type="checkbox"/> See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	<input type="checkbox"/> See attached schedule
End date of extended validity/transition period	<input type="checkbox"/> See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*<sup>2</sup>
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➤ **Directive Certificate(s)** as listed above or in the attached schedule.

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

*Choose applicable statements:*

- ☐ Expired *before* 20 March 2023:
  - ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or
  - ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or

<sup>2</sup> The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

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- ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

*Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:*

- ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

- ☒ Expired/expires *after* 20 March 2023:

*Choose one applicable statement:*

- ☒ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

## ➤ **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

*Choose one applicable statement:*

- ☒ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.





➤ **Quality Management System (QMS)**

Choose one applicable statement:

- ☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.
- ☐ A QMS in accordance with Article 10(9) MDR is in place.
- ☒ A notified body has issued the attached certificate for the MDR-compliant QMS.

➤ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

SIGNATURE SECTION			
<b>Place of Issue</b>	Guaynabo, Puerto Rico, USA		
<b>Signature</b>	<i>Electronically signed by: M KIMBERLY SHOEMAKER</i> <i>Reason: I am approving this document</i> <i>M KIMBERLY SHOEMAKER</i>	<b>Date</b>	See e-signature
<b>Name/Title</b>	Kim Shoemaker, Senior Director Regulatory Affairs kshoema1@its.jnj.com		
<b>Signature</b>	<i>Electronically signed by: MARJORIE MEDINA</i> <i>Reason: I am approving this document</i> <i>MARJORIE MEDINA</i>	<b>Date</b>	See e-signature
<b>Name/Title</b>	Marjorie Medina, Senior Director Quality Source MD mmedina6@its.jnj.com		
	Manufacturer's Person Responsible for Regulatory Compliance		
REVISION HISTORY			
<b>Revision</b>			
<b>A</b>	Original Version (Windchill # 501479326)		
<b>B</b>	Revised to include additional product codes (NSLX125S, NSLX137S, NSLX125C, NSLX137C, NSLX145C, HAR1120, HAR1136, HARHPBL, HARHPBLCN, HARHPGR, HARHPGRCN, NSLG2C35A, NSLG2C45A, NSLG2S35A, NSLG2S45A)** Note: Changed Revision History from Rev 0 to Rev A for internal documentation tracking purposes. Added Windchill #.		



## Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s) <sup>3</sup> (e.g., device name, family/group name device model or catalogue number)		Directive Certificate number(s) to which this confirmation is made (if applicable)	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable)	Notified Body name and number that issued the Directive Certificate (if applicable)	Notified Body name and number where the MDR application was lodged/contract signed (if applicable)	End date of extended validity / transition period	Substitute Device(s) (if applicable)
<b>10AG</b>	Code	Name	Certificate Cat.	G1 057666 0061	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	n/a
	Endopath 10MM Anvil Grasper with Ratchet Handle	Instruments for Minimally Invasive Endoscopic Procedures (Surgical or through natural body orifices)	Minimally Invasive Endoscopic Procedures (Surgical or through natural body orifices)				
<b>10BB</b>	Code	Name	Certificate Cat.	G1 057666 0061	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	n/a
	Endopath 10MM Babcock with Ratchet Handle	Instruments for Minimally Invasive Endoscopic Procedures (Surgical or through natural body orifices)	Minimally Invasive Endoscopic Procedures (Surgical or through natural body orifices)				
<b>2B12LT</b>	Code	Name	Certificate Cat.	G1 057666 0061	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	n/a
	ENDOPATH XCEL WITH OPTIVIEW TECHNOLOGY Bladeless Trocar with Stability Sleeve, 12mm, 100mm shaft length	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing				

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)



Identification of the device(s) <sup>3</sup> (e.g., device name, family/group name device model or catalogue number)		Directive Certificate number(s) to which this confirmation is made (if applicable)	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable)	Notified Body name and number that issued the Directive Certificate (if applicable)	Notified Body name and number where the MDR application was lodged/contract signed (if applicable)	End date of extended validity / transition period	Substitute Device(s) (if applicable)
<b>2B12XT</b>	Name	Certificate Cat.					
	ENDOPATH XCEL WITH OPTIVIEW TECHNOLOGY Bladeless Trocar with Stability Sleeve, 12mm, 150mm shaft length	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>2B5LT</b>	Name	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
	ENDOPATH XCEL WITH OPTIVIEW TECHNOLOGY Bladeless Trocar with Stability Sleeve, 5mm, 100mm shaft length						
<b>2B55T</b>	Name	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
	ENDOPATH XCEL WITH OPTIVIEW TECHNOLOGY Bladeless Trocar with Stability Sleeve, 5mm, 75mm shaft length						
<b>2B5XT</b>	Name	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
	ENDOPATH XCEL WITH OPTIVIEW TECHNOLOGY Bladeless Trocar with Stability Sleeve, 5mm, 150mm shaft length						



Identification of the device(s) <sup>3</sup> (e.g., device name, family/group name device model or catalogue number)		Directive Certificate number(s) to which this confirmation is made (if applicable)	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable)	Notified Body name and number that issued the Directive Certificate (if applicable)	Notified Body name and number where the MDR application was lodged/contract signed (if applicable)	End date of extended validity / transition period	Substitute Device(s) (if applicable)
Code	Name	Certificate Cat.					
<b>2CB12LT</b>	ENDOPATH XCEL WITH OPTIVIEW TECHNOLOGY Universal Trocar Stability Sleeve, 12mm, 100mm shaft length	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	n/a
<b>2CB5LT</b>	ENDOPATH XCEL WITH OPTIVIEW TECHNOLOGY Universal Trocar Stability Sleeve, 5mm, 100mm shaft length	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	n/a
<b>2CB5ST</b>	ENDOPATH XCEL WITH OPTIVIEW TECHNOLOGY Universal Trocar Stability Sleeve, 5mm, 75mm shaft length	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	n/a
<b>2D12LT</b>	ENDOPATH XCEL WITH OPTIVIEW TECHNOLOGY Dilating Tip Trocar with Stability Sleeve, 12mm, 100mm shaft length	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	n/a



Identification of the device(s) <sup>3</sup> (e.g., device name, family/group name device model or catalogue number)		Directive Certificate number(s) to which this confirmation is made (if applicable)	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable)	Notified Body name and number that issued the Directive Certificate (if applicable)	Notified Body name and number where the MDR application was lodged/contract signed (if applicable)	End date of extended validity / transition period	Substitute Device(s) (if applicable)
<b>2D12XT</b>	Name	Certificate Cat.					
	ENDOPATH XCEL WITH OPTIVIEW TECHNOLOGY Dilating Tip Trocar with Stability Sleeve, 12mm, 150mm shaft length	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>2D5LT</b>	Name	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
	ENDOPATH XCEL WITH OPTIVIEW TECHNOLOGY Dilating Tip Trocar with Stability Sleeve, 5mm, 100mm shaft length						
<b>2D5ST</b>	Name	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
	ENDOPATH XCEL WITH OPTIVIEW TECHNOLOGY Dilating Tip Trocar with Stability Sleeve, 5mm, 75mm shaft length						
<b>2H12LP</b>	Name	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
	ENDOPATH XCEL WITH OPTIVIEW TECHNOLOGY Blunt Tip Trocar with Smooth Sleeve, 12mm, 100mm length						



Identification of the device(s) <sup>3</sup> (e.g., device name, family/group name device model or catalogue number)		Directive Certificate number(s) to which this confirmation is made (if applicable)	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable)	Notified Body name and number that issued the Directive Certificate (if applicable)	Notified Body name and number where the MDR application was lodged/contract signed (if applicable)	End date of extended validity / transition period	Substitute Device(s) (if applicable)
<b>5BB</b>	Code	Certificate Cat.					
	Endopath 5MM Babcock with Ratchet Handle	Instruments for Minimally Invasive Endoscopic Procedures (Surgical or through natural body orifices)	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>5DCD</b>	ENDOPATH 5mm Curved Dissector with Monopolar Cautery	Electrosurgical Devices and Accessories	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>5DCS</b>	ENDOPATH 5mm Curved Scissors with Monopolar Cautery	Electrosurgical Devices and Accessories	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>5DSG</b>	Endopath 5MM Grasper with Ratchet Handle	Instruments for Minimally Invasive Endoscopic Procedures (Surgical or through natural body orifices)	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>ATS45</b>	ENDOPATH®ETS-Flex45 Endoscopic Articulating Linear Cutter	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a



Identification of the device(s) <sup>3</sup> (e.g., device name, family/group name device model or catalogue number)		Directive Certificate number(s) to which this confirmation is made (if applicable)	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable)	Notified Body name and number that issued the Directive Certificate (if applicable)	Notified Body name and number where the MDR application was lodged/contract signed (if applicable)	End date of extended validity / transition period	Substitute Device(s) (if applicable)
<b>B11LP</b>	Code	Certificate Cat.					
	ENDOPATH XCEL Bladeless Trocar with Smooth Sleeve, 11mm, 100mm length	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>B11LPH</b>	ENDOPATH XCEL Bladeless Trocar with Stability Sleeve, 11mm, 100mm length, handled	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
	ENDOPATH XCEL Bladeless Trocar with Stability Sleeve, 11mm, 100mm length	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>B11LTH</b>	ENDOPATH XCEL Bladeless Trocar with Smooth Sleeve, 11mm, 100mm length, handled	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
	ENDOPATH XCEL Bladeless Trocar with Smooth Sleeve, 12mm, 100mm length	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>B12LP</b>	ENDOPATH XCEL Bladeless Trocar with Smooth Sleeve, 12mm, 100mm length	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
	ENDOPATH XCEL Bladeless Trocar with Smooth Sleeve, 12mm, 100mm length, handled	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a



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<b>B12LT</b>	Code	Certificate Cat.					
	ENDOPATH XCEL Bladeless Trocar with Stability Sleeve, 12mm, 100mm length	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>B12LTH</b>	ENDOPATH XCEL Bladeless Trocar with Stability Sleeve, 12mm, 100mm length, handled	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
	ENDOPATH XCEL Bladeless Trocar with Stability Sleeve, 12mm, 75mm length	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>B12XT</b>	ENDOPATH XCEL Bladeless Trocar with Stability Sleeve, 12mm, 150mm length	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
	ENDOPATH XCEL Bladeless Trocar with Stability Sleeve, 15mm, 100mm length	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>B5LT</b>	ENDOPATH XCEL Bladeless Trocar with Stability Sleeve, 5mm, 100mm length	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a





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<b>B5ST</b>	ENDOPATH XCEL Bladeless Trocar with Stability Sleeve, 5mm, 75mm length	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>B5XT</b>	ENDOPATH XCEL Bladeless Trocar with Stability Sleeve, 5mm, 150mm length	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>B8LT</b>	ENDOPATH XCEL Bladeless Trocar with Stability Sleeve, 8mm, 100mm length	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>BCD10</b>	Endopath 10MM Blunt Cherry Dissector	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>BD05</b>	Endopath 5 MM Endoscopic Blunt Tip Dissectors	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a



Identification of the device(s) <sup>3</sup> (e.g., device name, family/group name device model or catalogue number)		Directive Certificate number(s) to which this confirmation is made (if applicable)	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable)	Notified Body name and number that issued the Directive Certificate (if applicable)	Notified Body name and number where the MDR application was lodged/contract signed (if applicable)	End date of extended validity / transition period	Substitute Device(s) (if applicable)
<b>CB11LT</b>	Code	Certificate Cat.					
	ENDOPATH XCEL Universal Trocar Stability Sleeve, 11mm, 100mm length	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>CB12LT</b>	Code	Certificate Cat.					
	ENDOPATH XCEL Universal Trocar Stability Sleeve, 12mm, 100mm length	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>CB5LT</b>	Code	Certificate Cat.					
	ENDOPATH XCEL Universal Trocar Stability Sleeve, 5mm, 100mm length	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>CB5ST</b>	Code	Certificate Cat.					
	ENDOPATH XCEL Universal Trocar Stability Sleeve, 5mm, 75mm length	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>CDH21A</b>	Code	Certificate Cat.					
	Ethicon Endo-Surgery Curved Intraluminal Staplers (ILS) (21mm)	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>CDH21B</b>	Code	Certificate Cat.					
	Ethicon Circular Stapler, 21 mm	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a



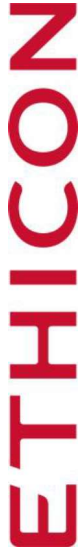
Identification of the device(s) <sup>3</sup> (e.g., device name, family/group name device model or catalogue number)		Directive Certificate number(s) to which this confirmation is made (if applicable)	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable)	Notified Body name and number that issued the Directive Certificate (if applicable)	Notified Body name and number where the MDR application was lodged/contract signed (if applicable)	End date of extended validity / transition period	Substitute Device(s) (if applicable)
<b>CDH23P</b>	Code	Certificate Cat.					
	Echelon Circular Powered Stapler, 23mm	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>CDH25A</b>	Ethicon Endo-Surgery Curved Intraluminal Staplers (ILS) (25mm)	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
	Ethicon Circular Stapler, 25 mm	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>CDH25P</b>	Echelon Circular Powered Stapler, 25mm	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
	Ethicon Endo-Surgery Curved Intraluminal Staplers (ILS) (29mm)	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>CDH29B</b>	Ethicon Circular Stapler, 29 mm	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a



Identification of the device(s) <sup>3</sup> (e.g., device name, family/group name device model or catalogue number)		Directive Certificate number(s) to which this confirmation is made (if applicable)	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable)	Notified Body name and number that issued the Directive Certificate (if applicable)	Notified Body name and number where the MDR application was lodged/contract signed (if applicable)	End date of extended validity / transition period	Substitute Device(s) (if applicable)
<b>CDH29P</b>	Code	Certificate Cat.					
	Echelon Circular Powered Stapler, 29mm	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>CDH31P</b>	Code	Certificate Cat.					
	Echelon Circular Powered Stapler, 31mm	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>CDH33A</b>	Code	Certificate Cat.					
	Ethicon Endo-Surgery Curved Intraluminal Staplers (ILS) (33mm)	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>CDH33B</b>	Code	Certificate Cat.					
	Ethicon Circular Stapler, 33 mm	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>CR40B</b>	Code	Certificate Cat.					
	CONTOUR Curved Cutter Stapler Reload (Standard), with knife	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>CR40G</b>	Code	Certificate Cat.					
	CONTOUR Curved Cutter Stapler Reload (Thick), with knife	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a



Identification of the device(s) <sup>3</sup> (e.g., device name, family/group name device model or catalogue number)		Directive Certificate number(s) to which this confirmation is made (if applicable)	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable)	Notified Body name and number that issued the Directive Certificate (if applicable)	Notified Body name and number where the MDR application was lodged/contract signed (if applicable)	End date of extended validity / transition period	Substitute Device(s) (if applicable)
<b>CS40B</b>	Code	Certificate Cat.					
	CONTOUR Curved Cutter Stapler	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>CS40G</b>	CONTOUR Curved Cutter Stapler	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>D11LT</b>	ENDOPATH XCEL Dilating Tip Trocar with Stability Sleeve, 11mm, 100mm length	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>D12LT</b>	ENDOPATH XCEL Dilating Tip Trocar with Stability Sleeve, 12mm, 100mm length	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>D12XT</b>	ENDOPATH XCEL Dilating Tip Trocar with Stability Sleeve, 12mm, 150mm length	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>D5LT</b>	ENDOPATH XCEL Dilating Tip Trocar with Stability Sleeve, 5mm, 100mm length	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a



Identification of the device(s) <sup>3</sup> (e.g., device name, family/group name device model or catalogue number)		Directive Certificate number(s) to which this confirmation is made (if applicable)	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable)	Notified Body name and number that issued the Directive Certificate (if applicable)	Notified Body name and number where the MDR application was lodged/contract signed (if applicable)	End date of extended validity / transition period	Substitute Device(s) (if applicable)
<b>D5ST</b>	ENDOPATH XCEL Dilating Tip Trocar with Stability Sleeve, 5mm, 75mm length	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>EC45A</b>	ECHELON FLEX 45 ENDOPATH Stapler Articulating Endoscopic Linear Cutter	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>EC45AL</b>	ECHELON FLEX 45 ENDOPATH Stapler Long Articulating Endoscopic Linear Cutter	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>EC60A</b>	ECHELON FLEX 60 ENDOPATH Stapler Articulating Endoscopic Linear Cutter	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>ECS21A</b>	Ethicon Endo-Surgery Endoscopic Curved Intraluminal Staplers (ILS) (21mm)	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a

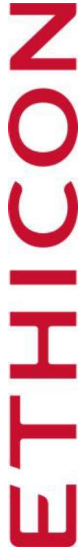


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<b>ECS21B</b>	Code	Certificate Cat.					
	Ethicon Circular Stapler, XL Sealed, 21 mm	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>ECS25A</b>	Ethicon Endo-Surgery Endoscopic Curved Intraluminal Staplers (ILS) (25mm)	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
	Ethicon Circular Stapler, XL Sealed, 25 mm	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>ECS29A</b>	Ethicon Endo-Surgery Endoscopic Curved Intraluminal Staplers (ILS) (29mm)	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
	Ethicon Circular Stapler, XL Sealed, 29 mm	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a

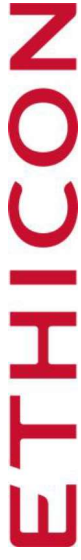


Identification of the device(s) <sup>3</sup> (e.g., device name, family/group name device model or catalogue number)		Directive Certificate number(s) to which this confirmation is made (if applicable)	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable)	Notified Body name and number that issued the Directive Certificate (if applicable)	Notified Body name and number where the MDR application was lodged/contract signed (if applicable)	End date of extended validity / transition period	Substitute Device(s) (if applicable)
<b>ECS33A</b>	Ethicon Endo-Surgery	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
	Endoscopic Curved Intraluminal Staplers (ILS) (33mm)						
<b>ECS33B</b>	Ethicon Circular Stapler, XL Sealed, 33 mm	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>EL5ML</b>	LIGAMAX-5 5MM Endoscopic Multiple Clip Applier	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>EPH02</b>	ENDOPATH Electrosurgery Probe Plus II Pistol Grip Handles, Hand Control	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>EPH04</b>	ENDOPATH Electrosurgery Probe Plus II Pencil Grip Handles, Hand Control	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>EPS01</b>	ENDOPATH Electrosurgery Probe Plus II, 5 mm Hook, 34 cm length	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a





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Code	Name	Certificate Cat.					
<b>EPS02</b>	ENDOPATH Electrosurgery Probe Plus II, 5 mm Spatula, 34 cm length	Electrosurgical Devices and Accessories	G1 057666 0061	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>EPS03</b>	ENDOPATH Electrosurgery Probe Plus II, 5 mm Right Angle, 34 cm length	Electrosurgical Devices and Accessories	G1 057666 0061	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>EPS04</b>	ENDOPATH Electrosurgery Probe Plus II, 5 mm Curved Dissector, 34 cm length	Electrosurgical Devices and Accessories	G1 057666 0061	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>EPS05</b>	ENDOPATH Electrosurgery Probe Plus II, 5 mm Hook, 29 cm length	Electrosurgical Devices and Accessories	G1 057666 0061	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>EPS06</b>	ENDOPATH Electrosurgery Probe Plus II, 5 mm Spatula, 29 cm length	Electrosurgical Devices and Accessories	G1 057666 0061	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>EPS07</b>	ENDOPATH Electrosurgery Probe Plus II, 5 mm Right Angle, 29 cm length	Electrosurgical Devices and Accessories	G1 057666 0061	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a



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<b>ER320</b>	Code	Certificate Cat.					
	10-M/L 10MM Endoscopic Rotating Multiple Clip Applier	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>ER420</b>	12-L 12MM Endoscopic Rotating Multiple Clip Applier	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>FLR01</b>	DEXTRUS™ Fixed-Length Retractor Small (up to 4.0 cm abdominal wall thickness)	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>FLR02</b>	DEXTRUS™ Fixed-Length Retractor Medium (4.0 - 7.0 cm abdominal wall thickness)	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>FLR03</b>	DEXTRUS™ Fixed-Length Retractor Large (greater than 7.0 cm abdominal wall thickness)	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>GCR40B</b>	Echelon CONTOUR Curved Cutter Stapler Reload blue (Standard)	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a



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<b>GCR40G</b>	Echelon CONTOUR Curved Cutter Stapler Reload Green (Thick)	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
	Echelon CONTOUR Curved Cutter Stapler with Blue Reload	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>GCS40G</b>	Echelon CONTOUR Curved Cutter Stapler with Green Reload	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>GEN11</b>	Generator G11	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>H12LP</b>	ENDOPATH XCEL Blunt Tip Trocar with Smooth Sleeve, 12mm, 100mm length	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a



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<b>HAP02</b>	Name	Certificate Cat.					
	DEXTRUS™ Seal Cap Assembly with Accessories (Marking Pen, Ruler, and Foam Wrap)	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>HAR17F</b>	Harmonic FOCUS Long Shears + Adaptive Tissue Technology	Ultrasonic Surgical Devices and Accessories	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>HAR23</b>	Harmonic ACE 5 mm Diameter Shears 23 cm Length + Adaptive Tissue Technology	Ultrasonic Surgical Devices and Accessories	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>HAR36</b>	Harmonic ACE Laparoscopic 5 mm Diameter Shears 36 cm Length + Adaptive Tissue Technology	Ultrasonic Surgical Devices and Accessories	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>HAR9F</b>	Harmonic FOCUS Shears + Adaptive Tissue Technology	Ultrasonic Surgical Devices and Accessories	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>HARH23</b>	Harmonic ACE+7, 5 mm Diameter Shears 23 cm Length with Advanced Hemostasis	Ultrasonic Surgical Devices and Accessories	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a



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<b>HARH36</b>	Code	Certificate Cat.					
	Harmonic ACE+7, Laparoscopic 5 mm Diameter Shears 36 cm Length with Advanced Hemostasis	Ultrasound Surgical Devices and Accessories	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>HARH45</b>	Code	Certificate Cat.					
	Harmonic ACE+7, Laparoscopic 5 mm Diameter Shears 45 cm Length with Advanced Hemostasis	Ultrasound Surgical Devices and Accessories	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>HARHD20</b>	Code	Certificate Cat.					
	HARMONIC® HD 1000i Shears, 5mm diameter, 20cm shaft length	Ultrasound Surgical Devices and Accessories	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>HARHD36</b>	Code	Certificate Cat.					
	HARMONIC® HD 1000i Shears, 5mm diameter, 36cm shaft length	Ultrasound Surgical Devices and Accessories	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>HDH05</b>	Code	Certificate Cat.					
	HARMONIC Laparoscopic Dissecting Hook, 5 mm diameter, 32cm shaft length.	Ultrasound Surgical Devices and Accessories	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>HP054</b>	Code	Certificate Cat.					
	HARMONIC Hand Piece	Ultrasound Surgical Devices and Accessories	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a



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Code	Name	Certificate Cat.					
<b>HP054CN</b>	HARMONIC Hand Piece	Ultrasonic Surgical Devices and Accessories	G1 057666 0061	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>HPBLUE</b>	HARMONIC Blue Hand Piece	Ultrasonic Surgical Devices and Accessories	G1 057666 0061	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>HPBLUECN</b>	HARMONIC Blue Hand Piece	Ultrasonic Surgical Devices and Accessories	G1 057666 0061	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>K11LT</b>	ENDOPATH XCEL Dilating Tip Trocar Pak, 11mm m, 100mm length containing: 1 Dilating Tip Trocar, 1 Universal Trocar Stability Sleeve	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>K12LT</b>	ENDOPATH XCEL Dilating Tip Trocar Pak, 12mm, 100mm length containing: 1 Dilating Tip Trocar with Stability Sleeve, 1 Stability Sleeve for Dilating Tip Trocar	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a

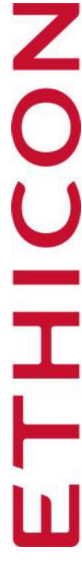


Identification of the device(s) <sup>3</sup> (e.g., device name, family/group name device model or catalogue number)		Directive Certificate number(s) to which this confirmation is made (if applicable)	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable)	Notified Body name and number that issued the Directive Certificate (if applicable)	Notified Body name and number where the MDR application was lodged/contract signed (if applicable)	End date of extended validity / transition period	Substitute Device(s) (if applicable)
<b>K5LT</b>	Name	Certificate Cat.					
	ENDOPATH XCEL Dilating Tip Trocar Pak, 5mm, 100mm length, containing: 1 Dilating Tip Trocar, 1 Universal Trocar Stability Sleeve	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>K5ST</b>	Name	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
	ENDOPATH XCEL Dilating Tip Trocar Pak 5mm, 75mm length, containing: 1 Dilating Tip Trocar, 1 Universal Trocar Stability Sleeve						
<b>LONG60A</b>	Name	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
	ECHELON FLEX 60 ENDOPATH Stapler Long Articulating Endoscopic Linear Cutter						
<b>LT100</b>	Name	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
	LIGACLIP EXTRA Ligating Clip Cartridge Titanium Small 6 Clips						
<b>LT102</b>	Name	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
	LIGACLIP EXTRA Ligating Clip Cartridge Titanium Small 20 Clips						

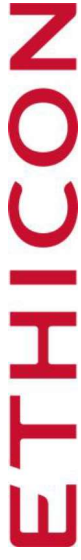


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<b>LT200</b>	LIGACLIP EXTRA Ligating Clip Cartridge Titanium Medium 6 Clips	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
	LIGACLIP EXTRA Ligating Clip Cartridge Titanium Medium 20 Clips	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>LT300</b>	LIGACLIP EXTRA Ligating Clip Cartridge Titanium Medium/Large	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
	LIGACLIP EXTRA Ligating Clip Cartridge Titanium Large	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>MCL20</b>	LIGACLIP® MCA Multiple Clip Applier / 33.7 cm, 20 Large Titanium Clips	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
	LIGACLIP® MCA Multiple Clip Applier / 29.2 cm, 20 Medium Titanium Clips	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a





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<b>MCM30</b>	LIGACLIP® MCA, Multiple Clip Applier / 29.2 cm, 30 Medium Titanium Clips	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>MCS20</b>	LIGACLIP® MCA, Multiple Clip Applier / 23.8 cm, 20 Small Titanium Clips	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>MSM20</b>	LIGACLIP® MCA, Multiple Clip Applier / 23.8 cm, 20 Medium Titanium Clips	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>NSLX120L</b>	ENSEAL® X1 Large Jaw Tissue Sealer 20cm Shaft Length	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>NTLC55</b>	Ethicon Endo-Surgery, LLC Linear Cutter for use with Selectable Reload, 55 mm	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>NTLC75</b>	Ethicon Endo-Surgery, LLC Linear Cutter for use with Selectable Reload, 75 mm	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a



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<b>PCE45A</b>	Code	Certificate Cat.					
	ECHELON FLEX 45 Powered ENDOPATH Stapler Compact Articulating Endoscopic Linear Cutter	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	n/a
<b>PCE60A</b>	Code	Certificate Cat.					
	ECHELON FLEX 60 Powered ENDOPATH Stapler Compact Articulating Endoscopic Linear Cutter	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	n/a
<b>PCEE45A</b>	Code	Certificate Cat.					
	ECHELON FLEX 45 Powered ENDOPATH Stapler Plus Compact Articulating Endoscopic Linear Cutter	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	n/a
<b>PCEE60A</b>	Code	Certificate Cat.					
	ECHELON FLEX 60 Powered ENDOPATH Stapler Plus Compact Articulating Endoscopic Linear Cutter	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	n/a
<b>PLE45A</b>	Code	Certificate Cat.					
	ECHELON FLEX 45 Powered Long Articulating Endoscopic Linear Cutter	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	n/a



Identification of the device(s) <sup>3</sup> (e.g., device name, family/group name device model or catalogue number)		Directive Certificate number(s) to which this confirmation is made (if applicable)	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable)	Notified Body name and number that issued the Directive Certificate (if applicable)	Notified Body name and number where the MDR application was lodged/contract signed (if applicable)	End date of extended validity / transition period	Substitute Device(s) (if applicable)
<b>PLE60A</b>	Code	Certificate Cat.					
	ECHELON FLEX 60 Powered Long Articulating Endoscopic Linear Cutter	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>PLEE45A</b>	Code	Certificate Cat.					
	ECHELON FLEX 45 Powered Plus Long Articulating Endoscopic Linear Cutter	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>PLEE60A</b>	Code	Certificate Cat.					
	ECHELON FLEX 60 Powered Plus Long Articulating Endoscopic Linear Cutter	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>PMR35</b>	Code	Certificate Cat.					
	PROXIMATE PLUS MD Multi-directional Release Skin Staplers	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>PMW35</b>	Code	Certificate Cat.					
	PROXIMATE PLUS MD Multi-directional Release Skin Staplers	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>PN120</b>	Code	Certificate Cat.					
	ENDOPATH® Pneumoneedle Insufflation Needle with Luer Lock Connector, 120mm	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a



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<b>PN150</b>	Code	Name	Certificate Cat.				
	ENDOPATH® Pneumoneedle Insufflation Needle with Luer Lock Connector, 150mm	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>POUCH</b>	ENDOPOUCH RETRIEVER® Specimen Retrieval Bag	Instruments for Minimally Invasive Endoscopic Procedures (Surgical or through natural body orifices)	G1 057666 0061	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
	PROXIMATE PPH Procedure for Prolapse and Hemorrhoids Set	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>PRR35</b>	PROXIMATE RH Rotating Head Skin Staplers (35 Regular)	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
	PROXIMATE RH Rotating Head Skin Staplers (35 Wide)	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a



Identification of the device(s) <sup>3</sup> (e.g., device name, family/group name device model or catalogue number)		Directive Certificate number(s) to which this confirmation is made (if applicable)	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable)	Notified Body name and number that issued the Directive Certificate (if applicable)	Notified Body name and number where the MDR application was lodged/contract signed (if applicable)	End date of extended validity / transition period	Substitute Device(s) (if applicable)
<b>PSE45A</b>	Code	Certificate Cat.					
	Name	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>PSE60A</b>	ECHELON FLEX 45 Powered ENDOPATH Stapler Articulating Endoscopic Linear Cutter	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
	ECHELON FLEX 60 Powered ENDOPATH Stapler Articulating Endoscopic Linear Cutter	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>PSEE45A</b>	Code	Certificate Cat.					
	Name	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>PSEE60A</b>	ECHELON FLEX 45 Powered ENDOPATH Stapler Plus Articulating Endoscopic Linear Cutter	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
	ECHELON FLEX 60 Powered ENDOPATH Stapler Plus Articulating Endoscopic Linear Cutter	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>PVE35A</b>	Code	Certificate Cat.					
	Name	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
	ECHELON FLEX Powered Vascular Stapler with Advanced Placement Tip	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a



Identification of the device(s) <sup>3</sup> (e.g., device name, family/group name device model or catalogue number)		Directive Certificate number(s) to which this confirmation is made (if applicable)	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable)	Notified Body name and number that issued the Directive Certificate (if applicable)	Notified Body name and number where the MDR application was lodged/contract signed (if applicable)	End date of extended validity / transition period	Substitute Device(s) (if applicable)
<b>PXR35</b>	Code	Certificate Cat.					
	PROXIMATE Skin Staplers (35 Regular)	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>PXW35</b>	PROXIMATE Skin Staplers (35 Wide)	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>SC45A</b>	ECHELON FLEX 45 ENDOPATH Stapler Compact Articulating Endoscopic Linear Cutter	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>SC60A</b>	ECHELON FLEX 60 ENDOPATH Stapler Compact Articulating Endoscopic Linear Cutter	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>SNGCB</b>	HARMONIC SYNERGY Curved Blade with Torque Wrench.	Ultrasonic Surgical Devices and Accessories	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>SNGHK</b>	HARMONIC SYNERGY Dissecting Hook with Torque Wrench	Ultrasonic Surgical Devices and Accessories	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a



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Code	Name Certificate Cat.						
<b>SNGHK2</b>	HARMONIC SYNERGY Combination Hook Blade with Torque Wrench	Ultrasonic Surgical Devices and Accessories	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	n/a
<b>UV120</b>	ENDOPATH® Ultra Veress Insufflation Needle with Luer Lock Connector, 120mm	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	n/a
<b>NSLX125S**</b>	ENSEAL X1 Tissue Sealer, Straight Jaw, 25 cm Shaft Length	Electrosurgical Devices and Accessories	G1 057666 0066	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	n/a
<b>NSLX137S**</b>	ENSEAL X1 Tissue Sealer, Straight Jaw, 37 cm Shaft Length	Electrosurgical Devices and Accessories	G1 057666 0066	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	n/a
<b>NSLX125C**</b>	ENSEAL X1 Tissue Sealer, Curved Jaw, 25 cm Shaft Length	Electrosurgical Devices and Accessories	G1 057666 0066	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	n/a
<b>NSLX137C**</b>	ENSEAL X1 Tissue Sealer, Curved Jaw, 37 cm Shaft Length	Electrosurgical Devices and Accessories	G1 057666 0066	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	n/a

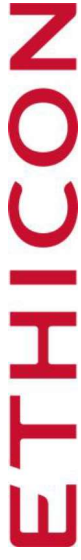


Identification of the device(s) <sup>3</sup> (e.g., device name, family/group name device model or catalogue number)		Directive Certificate number(s) to which this confirmation is made (if applicable)	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable)	Notified Body name and number that issued the Directive Certificate (if applicable)	Notified Body name and number where the MDR application was lodged/contract signed (if applicable)	End date of extended validity / transition period	Substitute Device(s) (if applicable)
<b>NSLX145C**</b>	ENSEAL X1 Tissue Sealer, Curved Jaw, 45 cm Shaft Length	Certificate Cat. Electrosurgical Devices and Accessories	G1 057666 0066	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
	<b>HAR1120**</b>	HARMONIC 1100 Shears, Integrated Hand Piece, 5mm diameter, 20cm shaft length	G1 057666 0061	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>HAR1136**</b>	HARMONIC 1100 Shears, Integrated Hand Piece, 5mm diameter, 36cm shaft length	Ultrasonic Surgical Devices and Accessories	G1 057666 0061	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>HARHPBL**</b>	HARMONIC Hand Piece, Blue	Ultrasonic Surgical Devices and Accessories	G1 057666 0061	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>HARHPBLCN**</b>	HARMONIC Hand Piece, Blue	Ultrasonic Surgical Devices and Accessories	G1 057666 0061	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>HARHPGR**</b>	HARMONIC Hand Piece, Gray	Ultrasonic Surgical Devices and Accessories	G1 057666 0061	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>HARHPGRCN**</b>	HARMONIC Hand Piece, Gray	Ultrasonic Surgical Devices and Accessories	G1 057666 0061	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a





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Code		Certificate Cat.					
	Name						
<b>NSLG2C35A**</b>	ENSEAL Laparoscopic 5 mm Diameter Articulating Tissue Sealer G2, 35 cm Length, Curved Jaw	Electrosurgical Devices and Accessories	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	n/a
<b>NSLG2C45A**</b>	ENSEAL Laparoscopic 5 mm Diameter Articulating Tissue Sealer G2, 45 cm Length, Curved Jaw	Electrosurgical Devices and Accessories	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	n/a
<b>NSLG2S35A**</b>	ENSEAL Laparoscopic 5 mm Diameter Articulating Tissue Sealer G2 35 cm Length Straight Jaw	Electrosurgical Devices and Accessories	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	n/a
<b>NSLG2S45A**</b>	ENSEAL Laparoscopic 5 mm Diameter Articulating Tissue Sealer G2, 45 cm Length, Straight Jaw	Electrosurgical Devices and Accessories	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	n/a



Identification of the device(s) <sup>3</sup> (e.g., device name, family/group name device model or catalogue number)		Directive Certificate number(s) to which this confirmation is made (if applicable)	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable)	Notified Body name and number that issued the Directive Certificate (if applicable)	Notified Body name and number where the MDR application was lodged/contract signed (if applicable)	End date of extended validity / transition period	Substitute Device(s) (if applicable)
<b>HSA08</b>	Code	Certificate Cat.	G2S 057666 0062	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
	Name	Accessories for Surgical devices for Instrument access, cutting, stapling, suturing and ultrasonic surgical devices					
<b>PSX</b>	Code	Certificate Cat.	G2S 057666 0062	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
	Name	Accessories for Surgical devices for Instrument access, cutting, stapling, suturing and ultrasonic surgical devices					
<b>VASECR35</b>	Code	Certificate Cat.	G1 057666 0061 G7 057666 0049	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2027	n/a
	Name	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing					
<b>SR55</b>	Code	Certificate Cat.	G1 057666 0061 G7 057666 0050	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2027	n/a
	Name	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing					



Identification of the device(s) <sup>3</sup> (e.g., device name, family/group name device model or catalogue number)			Directive Certificate number(s) to which this confirmation is made (if applicable)	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable)	Notified Body name and number that issued the Directive Certificate (if applicable)	Notified Body name and number where the MDR application was lodged/contract signed (if applicable)	End date of extended validity / transition period	Substitute Device(s) (if applicable)
Code	Name	Certificate Cat.						
SR75	Ethicon Endo-Surgery, Linear Cutter 75 Selectable Reload, (with knife)	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061 G7 057666 0050	05-26-2024 05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2027	n/a
	ENDOPATH ETS45 3.5 mm Reload (Standard), 6 Rows	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061 G7 057666 0054	05-26-2024 05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2027	n/a
ECR45M	ECHELON45 ENDOPATH Stapler Reload, gray - 2,0mm	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061 G7 057666 0054	05-26-2024 05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2027	n/a
	ECHELON60 ENDOPATH Stapler Reload, gray - 2,0mm	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061 G7 057666 0054	05-26-2024 05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2027	n/a
GST45B	ECHELON ENDOPATH Endoscopic Linear Cutter Reload, 45mm, with Gripping Surface Technology, blue – 3,6 mm	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061 G7 057666 0054	05-26-2024 05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2027	n/a



Identification of the device(s) <sup>3</sup> (e.g., device name, family/group name device model or catalogue number)		Directive Certificate number(s) to which this confirmation is made (if applicable)		Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable)		Notified Body name and number that issued the Directive Certificate (if applicable)		Notified Body name and number where the MDR application was lodged/contract signed (if applicable)		End date of extended validity / transition period		Substitute Device(s) (if applicable)	
Code	Name	Certificate Cat.		G1 057666 0061	G7 057666 0054	05-26-2024	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2027	n/a		
		Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	Endoscopic Linear Cutter Reload, 45mm, with Gripping Surface Technology, gold – 3,8 mm										
<b>GST45D</b>	ECHELON ENDOPATH Endoscopic Linear Cutter Reload, 45mm, with Gripping Surface Technology, gold – 3,8 mm	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	Endoscopic Linear Cutter Reload, 45mm, with Gripping Surface Technology, green – 4,1 mm	G1 057666 0061	G7 057666 0054	05-26-2024	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2027	n/a		
<b>GST45T</b>	ECHELON ENDOPATH Endoscopic Linear Cutter Reload, 45mm, with Gripping Surface Technology, black – 4,2 mm	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	Endoscopic Linear Cutter Reload, 45mm, with Gripping Surface Technology, white – 2,6 mm	G1 057666 0061	G7 057666 0054	05-26-2024	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2027	n/a		
<b>GST45W</b>	ECHELON ENDOPATH Endoscopic Linear Cutter Reload, 45mm, with Gripping Surface Technology, white – 2,6 mm	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing		G1 057666 0061	G7 057666 0054	05-26-2024	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2027	n/a		



Identification of the device(s) <sup>3</sup> (e.g., device name, family/group name device model or catalogue number)		Directive Certificate number(s) to which this confirmation is made (if applicable)	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable)	Notified Body name and number that issued the Directive Certificate (if applicable)	Notified Body name and number where the MDR application was lodged/contract signed (if applicable)	End date of extended validity / transition period	Substitute Device(s) (if applicable)
<b>GST60B</b>	Name	Certificate Cat.					
	ECHELON ENDOPATH Endoscopic Linear Cutter Reload with Gripping Surface Technology, blue – 3,6 mm	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061  G7 057666 0054	05-26-2024  05-26-2024	TÜV SÜD Product Service GmbH  0123	TÜV SÜD Product Service GmbH  0123	n/a
<b>GST60D</b>	Name	Certificate Cat.					
	ECHELON ENDOPATH Endoscopic Linear Cutter Reload with Gripping Surface Technology, gold – 3,8 mm	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061  G7 057666 0054	05-26-2024  05-26-2024	TÜV SÜD Product Service GmbH  0123	TÜV SÜD Product Service GmbH  0123	n/a
<b>GST60G</b>	Name	Certificate Cat.					
	ECHELON ENDOPATH Endoscopic Linear Cutter Reload with Gripping Surface Technology, green – 4,1 mm	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061  G7 057666 0054	05-26-2024  05-26-2024	TÜV SÜD Product Service GmbH  0123	TÜV SÜD Product Service GmbH  0123	n/a
<b>GST60T</b>	Name	Certificate Cat.					
	ECHELON ENDOPATH Endoscopic Linear Cutter Reload with Gripping Surface Technology, black – 4,2mm	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061  G7 057666 0054	05-26-2024  05-26-2024	TÜV SÜD Product Service GmbH  0123	TÜV SÜD Product Service GmbH  0123	n/a
<b>GST60W</b>	Name	Certificate Cat.					
	ECHELON ENDOPATH Endoscopic Linear Cutter Reload with Gripping Surface Technology, white – 2,6 mm	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061  G7 057666 0054	05-26-2024  05-26-2024	TÜV SÜD Product Service GmbH  0123	TÜV SÜD Product Service GmbH  0123	n/a



Identification of the device(s) <sup>3</sup> (e.g., device name, family/group name device model or catalogue number)		Directive Certificate number(s) to which this confirmation is made (if applicable)		Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable)		Notified Body name and number that issued the Directive Certificate (if applicable)		Notified Body name and number where the MDR application was lodged/contract signed (if applicable)		End date of extended validity / transition period		Substitute Device(s) (if applicable)	
Code	Name	Certificate Cat.											
<b>TR45G</b>	ENDOPATH ETS45 4.1 mm Reload (Thick)	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061 G7 057666 0054	05-26-2024 05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123		12-31-2027	n/a				
<b>TR45W</b>	ENDOPATH ETS45 2.5 mm Reload (Vascular/Thin)	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061 G7 057666 0054	05-26-2024 05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123		12-31-2027	n/a				
<b>TCD75</b>	PROXIMATE® Reloadable Linear Cutter with Safety Lock-Out, 75mm	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061 G7 057666 0056	05-26-2024 05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123		12-31-2027	n/a				
<b>TCR10</b>	PROXIMATE® Linear Cutter Reload (Standard), 100mm	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061 G7 057666 0056	05-26-2024 05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123		12-31-2027	n/a				
<b>TCR55</b>	PROXIMATE® Linear Cutter Reload (Standard), 55mm	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061 G7 057666 0056	05-26-2024 05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123		12-31-2027	n/a				
<b>TCR75</b>	PROXIMATE® Linear Cutter Reload (Standard), 75mm	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061 G7 057666 0056	05-26-2024 05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123		12-31-2027	n/a				



Identification of the device(s) <sup>3</sup> (e.g., device name, family/group name device model or catalogue number)		Directive Certificate number(s) to which this confirmation is made (if applicable)	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable)	Notified Body name and number that issued the Directive Certificate (if applicable)	Notified Body name and number where the MDR application was lodged/contract signed (if applicable)	End date of extended validity / transition period	Substitute Device(s) (if applicable)
<b>TCT10</b>	PROXIMATE® Reloadable Linear Cutter with Safety Lock-Out, 100mm	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2027	n/a
	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G7 057666 0056	05-26-2024				
<b>TCT55</b>	PROXIMATE® Reloadable Linear Cutter with Safety Lock-Out, 55mm	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2027	n/a
	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G7 057666 0056	05-26-2024				
<b>TCT75</b>	PROXIMATE® Reloadable Linear Cutter with Safety Lock-Out, 75mm	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2027	n/a
	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G7 057666 0056	05-26-2024				
<b>TLC10</b>	PROXIMATE® Reloadable Linear Cutter with Safety Lock-Out, 100mm	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2027	n/a
	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G7 057666 0056	05-26-2024				
<b>TLC55</b>	PROXIMATE® Reloadable Linear Cutter with Safety Lock-Out, 55mm	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2027	n/a
	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G7 057666 0056	05-26-2024				
<b>TLC75</b>	PROXIMATE® Reloadable Linear Cutter with Safety Lock-Out, 75mm	G1 057666 0061	05-26-2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2027	n/a
	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G7 057666 0056	05-26-2024				



Identification of the device(s) <sup>3</sup> (e.g., device name, family/group name device model or catalogue number)		Directive Certificate number(s) to which this confirmation is made (if applicable)	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable)	Notified Body name and number that issued the Directive Certificate (if applicable)	Notified Body name and number where the MDR application was lodged/contract signed (if applicable)	End date of extended validity / transition period	Substitute Device(s) (if applicable)
<b>TRD75</b>	Name PROXIMATE® Linear Cutter Reload (Gold), 75mm	Certificate Cat. Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2027	n/a
		G7 057666 0056	05-26-2024				
<b>TRT10</b>	Name PROXIMATE® Linear Cutter Reload (Thick), 100mm	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2027	n/a
		G7 057666 0056	05-26-2024				
<b>TRT55</b>	Name PROXIMATE® Linear Cutter Reload (Thick), 55mm	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2027	n/a
		G7 057666 0056	05-26-2024				
<b>TRT75</b>	Name PROXIMATE® Linear Cutter Reload (Thick), 75mm	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2027	n/a
		G7 057666 0056	05-26-2024				
<b>TVC55</b>	Name PROXIMATE® Reloadable Vascular Linear Cutter with Safety Lock-Out, 55mm	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2027	n/a
		G7 057666 0056	05-26-2024				
<b>TVR55</b>	Name PROXIMATE® Vascular Linear Cutter Reload, 55mm	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	12-31-2027	n/a
		G7 057666 0056	05-26-2024				





Identification of the device(s) <sup>3</sup> (e.g., device name, family/group name device model or catalogue number)		Directive Certificate number(s) to which this confirmation is made (if applicable)	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable)	Notified Body name and number that issued the Directive Certificate (if applicable)	Notified Body name and number where the MDR application was lodged/contract signed (if applicable)	End date of extended validity / transition period	Substitute Device(s) (if applicable)
<b>TX30B</b>	Name	Certificate Cat.					
	PROXIMATE Reloadable Linear Stapler, 30mm	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061 G7 057666 0056	05-26-2024 05-26-2024	TÜV SÜD Product Service GmbH 0123	12-31-2027	n/a
<b>TX30G</b>	PROXIMATE Reloadable Linear Stapler, 30mm	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061 G7 057666 0056	05-26-2024 05-26-2024	TÜV SÜD Product Service GmbH 0123	12-31-2027	n/a
	PROXIMATE Reloadable Vascular Linear Stapler, 30mm	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061 G7 057666 0056	05-26-2024 05-26-2024	TÜV SÜD Product Service GmbH 0123	12-31-2027	n/a
<b>TX60B</b>	PROXIMATE Reloadable Linear Stapler, 60mm	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061 G7 057666 0056	05-26-2024 05-26-2024	TÜV SÜD Product Service GmbH 0123	12-31-2027	n/a
	PROXIMATE Reloadable Linear Stapler, 60mm	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061 G7 057666 0056	05-26-2024 05-26-2024	TÜV SÜD Product Service GmbH 0123	12-31-2027	n/a
<b>XR30B</b>	PROXIMATE Linear Staplers Reload (Standard), 30mm	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061 G7 057666 0056	05-26-2024 05-26-2024	TÜV SÜD Product Service GmbH 0123	12-31-2027	n/a



Identification of the device(s) <sup>3</sup> (e.g., device name, family/group name device model or catalogue number)		Directive Certificate number(s) to which this confirmation is made (if applicable)	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable)	Notified Body name and number that issued the Directive Certificate (if applicable)	Notified Body name and number where the MDR application was lodged/contract signed (if applicable)	End date of extended validity / transition period	Substitute Device(s) (if applicable)
<b>XR30G</b>	Code	Name	Certificate Cat.				
	PROXIMATE Linear Staplers Reload, 30mm	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061 G7 057666 0056	05-26-2024 05-26-2024	TÜV SÜD Product Service GmbH 0123	12-31-2027	n/a
<b>XR30V</b>	PROXIMATE Vascular Linear Stapler Reload, 30mm	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061 G7 057666 0056	05-26-2024 05-26-2024	TÜV SÜD Product Service GmbH 0123	12-31-2027	n/a
<b>XR60B</b>	PROXIMATE Linear Stapler Reload, 60mm	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061 G7 057666 0056	05-26-2024 05-26-2024	TÜV SÜD Product Service GmbH 0123	12-31-2027	n/a
<b>XR60G</b>	PROXIMATE Linear Stapler Reload, 60mm	Surgical Devices for Instrument Access, Cutting, Stapling and Suturing	G1 057666 0061 G7 057666 0056	05-26-2024 05-26-2024	TÜV SÜD Product Service GmbH 0123	12-31-2027	n/a
<b>LX105</b>	LIGACLIP® Clip Applier Small 14.6 CM	n/a	n/a	n/a	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>LX107</b>	LIGACLIP® Clip Applier Small 19 CM	n/a	n/a	n/a	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a
<b>LX110</b>	LIGACLIP® Clip Applier Small	n/a	n/a	n/a	TÜV SÜD Product Service GmbH 0123	12-31-2028	n/a



Identification of the device(s) <sup>3</sup> (e.g., device name, family/group name device model or catalogue number)		Directive Certificate number(s) to which this confirmation is made (if applicable)	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable)	Notified Body name and number that issued the Directive Certificate (if applicable)	Notified Body name and number where the MDR application was lodged/contract signed (if applicable)	End date of extended validity / transition period	Substitute Device(s) (if applicable)
Code	Name	Certificate Cat.					
<b>LX130</b>	LIGACLIP® Clip Applier Right Angle Small	n/a	n/a	n/a	TUV SÜD Product Service GmbH	12-31-2028	n/a
<b>LX205</b>	LIGACLIP® Clip Applier Medium 14.6 CM	n/a	n/a	n/a	0123 TUV SÜD Product Service GmbH	12-31-2028	n/a
<b>LX207</b>	LIGACLIP® Clip Applier Medium 19 CM	n/a	n/a	n/a	0123 TUV SÜD Product Service GmbH	12-31-2028	n/a
<b>LX210</b>	LIGACLIP® Clip Applier Medium 26.7 CM	n/a	n/a	n/a	0123 TUV SÜD Product Service GmbH	12-31-2028	n/a
<b>LX220</b>	LIGACLIP® Clip Applier Medium Angled Jaw 26.7 CM	n/a	n/a	n/a	0123 TUV SÜD Product Service GmbH	12-31-2028	n/a
<b>LX230</b>	LIGACLIP® Clip Applier Angled Jaw Medium	n/a	n/a	n/a	0123 TUV SÜD Product Service GmbH	12-31-2028	n/a
<b>END</b>							

# ETHICON



Product Service

## EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

**No. G10 057666 0064 Rev. 03**

### Manufacturer:

**Ethicon Endo-Surgery, LLC**

475 Calle C  
00969 Guaynabo  
PUERTO RICO USA

### SRN Manufacturer:

US-MF-000013107

### Authorized Representative:

Johnson & Johnson Medical GmbH  
Robert-Koch-Strasse 1, 22851 Norderstedt, GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s). The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result. The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis. The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.  
For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:G10\\_057666\\_0064\\_Rev\\_03](http://www.tuvsud.com/ps-cert?q=cert:G10_057666_0064_Rev_03)

**Report No.:** 713223764 / 713271082

**Preceding Certificate No.:** G10 057666 0064 Rev. 02

**Valid from:** 2022-11-10

**Valid until:** 2026-01-14

**Date of Initial Issuance:** 2021-01-15

Christoph Dicks  
Head of Certification/Notified Body

**Issue date:** 2022-11-10

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TUV®

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# ETHICON

ZERTIFIKAT ♦ CERTIFICATE ♦ 認證證書 ♦ CERTIFICADO ♦ CERTIFICAT



## EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III  
(Class IIa and Class IIb Devices)

**No. G10 057666 0064 Rev. 03**

Classification:	IIa
Device Group:	H020101 - MECHANICAL SKIN STAPLERS
Intended Purpose:	N/A
Classification:	IIa
Device Group:	K010201 - MINIMALLY INVASIVE SURGERY SURGICAL INSTRUMENTS, SINGLE-USE
Intended Purpose:	N/A
Classification:	IIa
Device Group:	K010101 - TROCAR, SINGLE-USE
Intended Purpose:	N/A
Classification:	IIb
Device Group:	Z120109 - ELECTROSURGICAL INSTRUMENTS
Intended Purpose:	Intended to supply energy to the HARMONIC and ENSEAL surgical instruments
Classification:	IIb
Device Group:	K020101 - MONO- AND BIPOLAR SURGICAL INSTRUMENTS, SINGLE-USE
Intended Purpose:	Ligation and division of vessels; cut and seal vessels, cut, grasp, and dissect tissue during surgery; can be used on vessels (arteries, veins, pulmonary vasculature, lymphatics)
Classification:	IIb
Device Group:	K020201 - ULTRASONIC SURGERY INSTRUMENTS, SINGLE-USE
Intended Purpose:	Indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired
Classification:	IIb
Device Group:	Z120109 - ELECTROSURGICAL INSTRUMENTS
Intended Purpose:	Designed to convert electrical energy from a compatible HARMONIC™ Generator to mechanical motion for the instrument blades
Classification:	IIb
Device Group:	K020101 - MONO- AND BIPOLAR SURGICAL INSTRUMENTS, SINGLE-USE
Intended Purpose:	Intended for facilitating grasping, mobilization, dissection and transection of tissue

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TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123  
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# ETHICON



Product Service

## EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III  
(Class IIa and Class IIb Devices)

No. G10 057666 0064 Rev. 03

<b>Classification:</b>	IIb
<b>Device Group:</b>	K020101 - MONO- AND BIPOLAR SURGICAL INSTRUMENTS, SINGLE-USE
<b>Intended Purpose:</b>	Intended for facilitating tissue dissection, coagulation, irrigation and fluid evacuation through a common trocar sleeve

Classification:	IIb
Device Group:	H020203 - SEMICIRCULAR STAPLERS FOR OPEN SURGERY
Intended Purpose:	Intended for transection and resection of tissue

The validity of this certificate depends on conditions and/or is limited to the following:

Revision History:	Rev.	Dated	Report
	00	2021-01-15	713181354
	01	2022-03-04	713201749
	02	2022-03-08	713220847

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFICAT





## Certyfikat UE dla systemu zarządzania jakością (MDR - rozporządzenie w sprawie wyrobów medycznych — Medical Device Resolution)

Zgodnie z rozporządzeniem (UE) 2017/745 w sprawie wyrobów medycznych, Załącznik IX, rozdziały I i III (wyroby klasy IIa i IIb)

**Nr G10 057666 0064 wer. 03**

### Wytwórca:

**Ethicon Endo-Surgery, LLC**

475 Calle C  
00969 Guaynabo  
PORTORYKO USA

Niepowtarzalny numer rejestracyjny producenta: US-MF-000013107

### Upoważniony przedstawiciel:

Johnson & Johnson Medical GmbH  
Robert-Koch-Strasse 1, 22851 Norderstedt, NIEMCY

Jednostka certyfikująca, TÜV SÜD Product Service GmbH, zaświadcza, że ww. producent ustanowił, udokumentował i wdrożył system zarządzania jakością, opisany w art. 10 ust. 9 rozporządzenia (UE) 2017/745 w sprawie wyrobów medycznych. Dane szczegółowe dotyczące kategorii wyrobów objętych systemem zarządzania jakością są opisane na kolejnej stronie (kolejnych stronach)

Raport, do którego niniejszy dokument odwołuje się poniżej, podsumowuje wyniki oceny i zawiera odniesienia do właściwych certyfikatów, norm zharmonizowanych i raportów z badań. Ocena zgodności została przeprowadzona z wynikiem pomyślnym zgodnie z załącznikiem IX rozdział I i III ww. rozporządzenia.

Ocena systemu zarządzania jakością towarzyszyła ocena dokumentacji technicznej wybranych reprezentatywnie wyrobów.

Certyfikowany system zarządzania jakością podlega okresowym kontrolom ze strony TÜV SÜD Product Service GmbH. Ocena nadzoru obejmuje również ocenę dokumentacji technicznej danego wyrobu lub wyrobów na podstawie dalszych reprezentatywnych próbek. Należy przestrzegać wszystkich obowiązujących wymagań rozporządzenia w sprawie badań i certyfikacji Grupy TÜV SÜD. Szczegółowe informacje można znaleźć i [ważność](#) certyfikatu potwierdzić na stronie: [www.tuvsud.com/ps-cert?q=cert:G10 057666 0064 wer. 03](http://www.tuvsud.com/ps-cert?q=cert:G10 057666 0064 wer. 03)

**Nr raportu:** 713223764 / 713271082

**Numer poprzedniego certyfikatu:** G10 057666 0064 wer. 02

**Ważny od:** 2022-11-03

**Ważny do:** 2025-01-14

**Data wystawienia po raz pierwszy:** 2021-01-15

**Data wystawienia:**  
Certyfikującej/Notyfikowanej

Christoph Dicks  
2022-11-03 Dyrektor Jednostki



## Certyfikat UE dla systemu zarządzania jakością (MDR - rozporządzenie w sprawie wyrobów medycznych — Medical Device Resolution)

Zgodnie z rozporządzeniem (UE) 2017/745 w sprawie wyrobów medycznych, Załącznik IX, rozdziały I i III (wyroby klasy IIa i IIb)

**Nr G10 057666 0064 wer. 03**

<b>Klasyfikacja:</b>	IIa
<b>Grupa wyrobów:</b>	H020101 — MECHANICZNE STAPLERY DO SKÓRY
<b>Przeznaczenie:</b>	Nie dot.
<b>Klasyfikacja:</b>	IIa
<b>Grupa wyrobów:</b>	K010201 - NARZĘDZIA CHIRURGII MINIMALNIE INWAZYJNEJ, JEDNORAZOWEGO UŻYCIA
<b>Przeznaczenie:</b>	Nie dot.
<b>Klasyfikacja:</b>	IIa
<b>Grupa wyrobów:</b>	K010101 - TROKAR, JEDNORAZOWEGO UŻYCIA
<b>Przeznaczenie:</b>	Nie dotyczy
<b>Klasyfikacja:</b>	II b
<b>Grupa wyrobów:</b>	Z120109 - NARZĘDZIA ELEKTROCHIRURGICZNE
<b>Przeznaczenie:</b>	Zasilanie narzędzi chirurgicznych HARMONIC i ENSEAL
<b>Klasyfikacja:</b>	II b
<b>Grupa wyrobów:</b>	K020101 — NARZĘDZIA CHIRURGICZNE JEDNOBIEGUNOWE I DWUBIEGUNOWE JEDNORAZOWEGO UŻYTKU
<b>Przeznaczenie:</b>	Podwiązanie i dzielenie naczyń; przecinanie i uszczelnianie naczyń, cięcie, chwytanie i dyssekcja tkanek podczas operacji; można stosować na naczyniach (tętnice, żyły, naczynia płucne, limfatyczne)
<b>Klasyfikacja:</b>	II b
<b>Grupa wyrobów:</b>	K020201 — NARZĘDZIA CHIRURGICZNE ULTRADŹWIĘKOWE, JEDNORAZOWEGO UŻYTKU
<b>Przeznaczenie:</b>	Wskazane do nacinania tkanek miękkich, gdy pożądane jest tamowanie krwawienia i minimalne urazy termiczne
<b>Klasyfikacja:</b>	II b
<b>Grupa wyrobów:</b>	Z120109 - NARZĘDZIA ELEKTROCHIRURGICZNE
<b>Przeznaczenie:</b>	Zaprojektowane do przekształcania energii elektrycznej z kompatybilnego generatora HARMONIC™ w ruch mechaniczny ostrzy narzędzi
<b>Klasyfikacja:</b>	II b
<b>Grupa wyrobów:</b>	K020101 — NARZĘDZIA CHIRURGICZNE JEDNOBIEGUNOWE I DWUBIEGUNOWE JEDNORAZOWEGO UŻYTKU
<b>Przeznaczenie:</b>	Przeznaczone do ułatwiania chwytania, mobilizacji, dyssekcji i transsekcji tkanek





## Certyfikat UE dla systemu zarządzania jakością (MDR - rozporządzenie w sprawie wyrobów medycznych — Medical Device Resolution)

Zgodnie z rozporządzeniem (UE) 2017/745 w sprawie wyrobów medycznych, Załącznik IX,  
rozdziały I i III (wyroby klasy IIa i IIb)

**Nr G10 057666 0064 wer. 03**

<b>Klasyfikacja:</b>	II b	
<b>Grupa wyrobów:</b>	K020101 — NARZĘDZIA CHIRURGICZNE JEDNOBIEGUNOWE I DWUBIEGUNOWE JEDNORAZOWEGO UŻYTKU	
<b>Zastosowanie zgodne z przeznaczeniem:</b>	Przeznaczone do ułatwienia dyssekcji tkanek, koagulacji, irygacji i ewakuacji płynów przez wspólną tuleję trokaru	
<b>Klasyfikacja:</b>	II b	
<b>Grupa wyrobów:</b>	H020203 - STAPLERY PÓŁOKRĄGŁE DO CHIRURGII OTWARTEJ	
<b>Przeznaczenie:</b>	Przeznaczone do transsekcji i resekcji tkanek	
<b>Historia zmian:</b>	wer.	Data      sprawozdania
	00	2021-01-15 713181354
	01	2022-03-04 713201749
	02	2022-03-08 713220847










# MDR amendment 2023\_607 EES Self Declaration Rev B\_2

Final Audit Report

2024-02-14

Created:	2024-02-14
By:	Johanna Schroeer (JSchroeer@its.jnj.com)
Status:	Signed
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## "MDR amendment 2023\_607 EES Self Declaration Rev B\_2" History

-  Document created by Johanna Schroeer (JSchroeer@its.jnj.com)  
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