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Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 062680 0156 Rev. 00

Manufacturer:

Baxter Healthcare SA

8010 Zürich
SWITZERLAND

**Product Category(ies): Non-Active Implants
Sterile Hemostatic Sealant of Animal
and Human Origin,
Surgical Sealant**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713154001

Valid from: 2020-03-24

Valid until: 2024-05-26

Date, 2020-03-24

Christoph Dicks
Head of Certification/Notified Body



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Product Service

EC Certificate

EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)

(Devices in Class III)

No. G7AO 062680 0106 Rev. 01

Manufacturer:

Baxter Healthcare SA

8010 Zürich
SWITZERLAND

Product:

Non-Active Implants

**Sterile Hemostatic Sealant of
Animal/Human Origin**

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with the directive 93/42/EEC Annex II (4) and Regulation (EU) 722/2012 on medical devices manufactured utilizing tissues of animal origin. The design of the devices conforms to the requirements of the Directive and the Regulation. If a certificate of the European Directorate for the Quality of Medicines (EDQM) has been issued for the respective material of animal origin, the validity of our certificate is associated with the validity of the EDQM certificate. Any changes of the EDQM certificate need to be reported immediately to TÜV SÜD Product Service GmbH by a change notification. For marketing of these devices an additional Annex II without (4) certificate is mandatory. See also notes overleaf.

Report no.:

713153955

Valid from:

2020-04-15

Valid until:

2024-05-26

Date,

2020-04-15

Christoph Dicks

Head of Certification/Notified Body



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Product Service

EC Certificate

EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)

(Devices in Class III)

No. G7AO 062680 0106 Rev. 01

Model(s):

**In accordance with the Directive 2000/70/EC on
medical devices incorporating stable derivatives
of human blood or human plasma**

Floseal Hemostatic Matrix, 5 ml

(Floseal VH S/D)

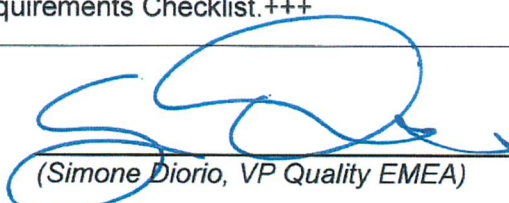
Floseal Hemostatic Matrix, 10 ml

(Floseal VH S/D)

Parameters:

- 1503353 5 ml
- 1503354 10 ml

Declaration of Conformity

According to:	Council Directive 93/42/EEC (MDD)
Annexes: II, section 4* and II, excluding 4	
Notified Body Certificate(s):	G7AO 062680 106 Rev.01* G1 062680 0156 Rev.00
Notified Body's name and address:	TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 Munich Germany
Notified Body's identification number:	0123
Manufacturer's name:	Baxter Healthcare SA
Manufacturer's address:	8010 Zürich Switzerland
EC Representative's address:	not applicable
+++We declare under our sole responsibility that the following product(s) conform to the applicable provisions of the above-mentioned Directive:+++	
Product Family/Category: Non-Active Implants, Sterile Hemostatic Sealant of Animal and Human Origin*, Non-Active Implants, Sterile Hemostatic Sealant of Animal and Human Origin, Surgical Sealant	
Code Numbers:	See "CE Marked Product Code List"
+++This declaration is made on the following basis:	
<ul style="list-style-type: none">• The validity of this document shall not start earlier than the validity date of the corresponding EC Certificate.• The DOC declares conformity to all product lots released within the above validity period.• For Class I non-sterile / non-measuring: self-declaration of conformity.• Compliance to standards and regulations as defined in the Technical Documentation and Essential Requirements Checklist.+++	
Signature:	 (Simone Diorio, VP Quality EMEA)
	<u>Zurich 21 Apr 2020</u> (Place, Date)

**CE-marked Product Code List
to the Declaration of Conformity**

Business: Advanced Surgery

Certificate Number:	G7AO 062680 0106 Rev.01* and G1 062680 0156 Rev.00
Conformity Assessment Procedure:	Annex II, section 4* and Annex II, excluding 4
Classification:	III
Sterilisation Method:	Gamma Irradiation, EtO, Steam
Facility:	Baxter Healthcare Corporation, Hayward (USA) Baxter AG, Vienna (Austria)
Product Category:	Non-Active Implants, Sterile Hemostatic Sealant of Animal and Human Origin* Non-Active Implants, Sterile Hemostatic Sealant of Animal and Human Origin, Surgical Sealant

Code	Description	Date of CE marking
1503353	Floseal Hemostatic Matrix, 5 ml (Floseal VH S/D)	see BaxTRACs
1503354	Floseal Hemostatic Matrix, 10 ml (Floseal VH S/D)	see BaxTRACs

This report has been reviewed and verified by

A. Frey-Niedzela Date: *21 April 2020*

(Annette Frey-Niedzela)

Senior Manager, Global Regulatory Affairs

PARENT DOCUMENT(S): **RA081DVC**
(current rev.)

OWNER CODE **RAP**

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BAXTER CONFIDENTIAL

FORM NO.: **RA082DVCFM**
REVISION: **A**
ISSUE DATE: **26-APR-2012**
EFFECTIVE DATE: **26-MAY-2012**