EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 628500**

Issued To: **PDI Ltd**
Aber Park
Flint
Flintshire
CH6 5EX
United Kingdom

In respect of:

Design, development and manufacture of non-sterile liquid impregnated disinfectant wipes for the disinfection of non-invasive medical devices.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President - Medical Devices

First Issued: **2015-11-05** Date: **2021-03-15** Expiry Date: **2024-05-26**

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Supplementary Information to CE 628500

Issued To:

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Number	Device Name	Intended purpose per IFU
Class IIa		
MD 0108	Super Sani-Cloth Plus Disinfectant wipe - canister	----------
MD 0108	Sani-Cloth 70 Disinfectant wipe - canister	----------
MD 0108	Sani-Cloth Active Disinfectant wipe – canister, Bucket, Doy bag	----------
MD 0108	Sani-Cloth CHG 2% Disinfectant wipe - sachet	----------
MD 0108	Sani-Cloth Chlor Disinfectant wipe - canister	----------
MD 0108	Sani-Cloth AF Universal Disinfectant wipe – Canister, Bucket, Flow-wrap	----------

First Issued: **2015-11-05** Date: **2021-03-15** Expiry Date: **2024-05-26**

By Royal Charter

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Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 628500**
Date:	**2021-03-15**
Issued To:	**PDI Ltd** **Aber Park** **Flint** **Flintshire** **CH6 5EX** **United Kingdom**

Subcontractor:	**Service(s) supplied**
Nex Medical Antiseptics Srl. Via Arluno, 37/39 20010 Casorezzo Milan Italy	**EU Representative**
PDI (EMEA) Ltd Pywell Road Willowbrook East Industrial Estate Corby NN17 5XJ United Kingdom	**Manufacture**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 628500**
Date: **2021-03-15**
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Aber Park
Flint
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Date	Reference Number	Action
05 November 2015	8266784	First issue.
07 February 2019	9628060	Traceable to NB 0086.
20 November 2019	3044874	Removed sterile devices from scope. Removed three subcontractors from list of critical subcontractors.
18 September 2020	3273939	Subcontractor Pluswipes Limited name change to PDI (EMEA) Ltd, Addition of supplementary information table. Addition of new product Sani-Cloth AF Universal.
22 October 2020	3219326	Renewal Addition of EU Representative Administrative correction to subcontractor's address Nice-Pak International Limited and PDI (EMEA) Ltd.,
15 March 2021	3372694	Removal of subcontractor Jonarve Limited, Flint, United Kingdom.

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Date	Reference Number	Action
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
06 December 2021	3564554	Change of legal manufacturer name and address. From: PDI Ltd, Aber Park Flint Flintshire CH6 5EX United Kingdom To: Professional Disposables International Ltd., Pywell Road Willowbrook Industrial Estate Corby NN17 5XJ United Kingdom Change of device name. From (before): Sani-Cloth CHG 2% To (current): Prevantics 2% CHG Removal of sub-contractor Nice-Pak International Limited., for the service of manufacture.

By Royal Charter

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Date	Reference Number	Action
06 April 2022	3661352	Change to information on the device table: Device name changed from Sani-Cloth AF universal to Sani-Cloth AF.

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Inspiring trust for a more resilient world.

6 April 2022

PDI Ltd
Aber Park
Flint
Flintshire
CH6 5EX
United Kingdom

To whom it may concern,

The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	Directive and Annex	Reference Number	Changes approved
CE 628500	93/42/EEC Annex II excluding 4	3661352	Change to information on the device table: Device name changed from Sani-Cloth AF universal to Sani-Cloth AF.

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Graeme Tunbridge
Senior Vice President, Medical Devices

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