

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: **2020-10-22**

Expiry Date: **2024-05-26**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

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Supplementary Information to CE 628500

Issued To:

**PDI Ltd
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United Kingdom**

| 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: **2020-10-22**Expiry Date: **2024-05-26**

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This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

EC Certificate - Full Quality Assurance System

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: **2020-10-22**
 Issued To: **PDI Ltd
 Aber Park
 Flint
 Flintshire
 CH6 5EX
 United Kingdom**

| Subcontractor: | Service(s) supplied |
|--|---------------------|
| Jonarve Ltd Castle Park Industrial Estate Flint Flintshire CH6 5XA United Kingdom | Manufacture |
| Nex Medical Antiseptics Srl. Via Arluno, 37/39 20010 Casorezzo Milan Italy | EU Representative |
| Nice-Pak International Limited Aber Park Aber Park Aber Road Flint CH6 5EX United Kingdom | Manufacture |

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List of Significant Subcontractors

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

Certificate No: **CE 628500**
 Date: **2020-10-22**
 Issued To: **PDI Ltd**
Aber Park
Flint
Flintshire
CH6 5EX
United Kingdom

Subcontractor:

Service(s) supplied

PDI (EMEA) Ltd
 Pywell Road
 Willowbrook East Industrial Estate
 Corby
 NN17 5XJ
 United Kingdom

Manufacture

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Certificate History

Certificate No: **CE 628500**
Date: **2020-10-22**
Issued To: **PDI Ltd
Aber Park
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Flintshire
CH6 5EX
United Kingdom**

| 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. |
| Current | 3219326 | Renewal Addition of EU Representative Administrative correction to subcontractor's address Nice-Pak International Limited and PDI (EMEA) Ltd., |

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