EC Design-Examination Certificate

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

No. **CE 552032**

Issued To: **Systagenix Wound Management Ltd**
Gargrave
North Yorkshire
BD23 3RX
United Kingdom

In respect of:

INADINE® - Povidone Iodine Non Adherent Dressing

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding 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: **2009-07-16** Date: **2021-05-25** Expiry Date: **2024-05-26**

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INADINE® - Povidone Iodine Non Adherent Dressing

Code Nos.

Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
P01481#	INADINE® PVP-I Non Adherent Dressing	5cm x 5cm	For the management of ulcerative wounds and for the prevention of infection in minor burns and minor traumatic skin loss injuries	Class III
P01491#	INADINE® PVP-I Non Adherent Dressing	9.5cm x 9.5cm		Class III
P01512#	INADINE® PVP-I Non Adherent Dressing	9.5cm x 9.5cm		Class III

# Indicates a product code may be followed by a suffix for a market-specific product coding.

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Certificate History

Date	Reference Number	Action
16 July 2009	10108855	First Issue. Based on original design examination certificate CE 01279 (Johnson & Johnson).
08 July 2011	10125072	Certificate renewal.
25 November 2011	10131106	Change to irradiation dose.
30 July 2013	10142620	Change to in-house processing of yarn raw material.
25 March 2015	10154158	Interleave formulation change.
28 June 2016	10161785	Certificate renewal and administrative update to list product sizing.
23 November 2016	10162701	Change to case configuration of product code P01512.
30 November 2017	8846259	Change of antioxidant in interleaves / release liners.
06 February 2019	7779589	Traceable to NB 0086.
16 October 2019	8923590	Reduction of pouch size, carton size and outer box size on the 5cm x 5cm product (P01481#)

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Date	Reference Number	Action
07 April 2020	3098689	Certificate renewal. Removal of "an affiliate of Systagenix Wound Management Manufacturing Limited" from the address. Addition of subcontractor for knitting, change to iodine test method and change to decontamination process. Administrative update to the product table (addition of Intended purpose per IFU)
31 August 2020	3271073	Addition of EU Authorised Representative, KCI Manufacturing, Ireland.
16 February 2021	3328130	Addition of insert leaflet indicating EU Rep and Importer details.

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Date	Reference Number	Action
Current	3405058	Continuation of the Recipharm Limited PVP-I ointment mixing process at the Ashton-under-Lyne site under the oversight of Systagenix Wound Management Manufacturing Limited. Replication of the PVP-I ointment mixing process at Systagenix Wound Management Manufacturing Limited, Gargrave.

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