By Royal Charter

EC Design-Examination Certificate

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

No. **CE 01105**

Issued To: **Smith & Nephew Medical Ltd**
101 Hessle Road
Hull
HU3 2BN
United Kingdom

In respect of:

Bactigras chlorhexidine acetate tulle gras 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: **1995-12-21** Date: **2020-01-30** Expiry Date: **2024-05-26**

...making excellence a habit.™

EC Design-Examination Certificate

Supplementary Information to CE 01105

Issued To:

Smith & Nephew Medical Ltd
101 Hessle Road
Hull
HU3 2BN
United Kingdom

Product: Bactigras chlorhexidine acetate tulle gras dressing

Catalogue Number	Device Name	Model, Type	Intended purpose	Classification
7456	Bactigras chlorhexidine acetate tulle gras dressing	5cm x 5cm dressing	For use as a topical treatment only. It is indicated for a wide range of wounds where there is a risk of infection, or on already infected wounds in conjunction with systemic antibacterial agents. The range of wounds on which BACTIGRAS may be used include: Minor burns and scalds Lacerations, abrasions and other skin loss wounds Donor and recipient graft sites	III
7457		10cm x 10cm dressing		
6003650		10cm x 10cm dressing		
7461		15cm x 20cm dressing		
60003661		10cm x 40cm dressing		
60007505		15cm x 1m roll		

First Issued: **1995-12-21** Date: **2020-01-30** Expiry Date: **2024-05-26**

...making excellence a habit.™

EC Design-Examination Certificate

Supplementary Information to CE 01105

Issued To:

Smith & Nephew Medical Ltd
101 Hessle Road
Hull
HU3 2BN
United Kingdom

Certificate History

Date	Reference Number	Action
21 December 1995	MD 000072	First issue.
20 March 1996	MD 000133	Change to packaging material.
9 May 1996	10032264	Change of Chlorhexidine Acetate supplier.
19 May 1997	Correspondence on Client File	Extension to product range.
21 December 2000	10019859	5 year renewal & change to testing regime.
17 May 2005	10032264	Addition of product codes and update to certificate format.
28 October 2005	10073624	5 year renewal.
12 December 2006	10079016	Extension of mass storage time to 35 days.
06 January 2011	10119364	5 year renewal.

First Issued: **1995-12-21** Date: **2020-01-30** Expiry Date: **2024-05-26**

EC Design-Examination Certificate

Supplementary Information to CE 01105

Issued To:

Smith & Nephew Medical Ltd
101 Hessle Road
Hull
HU3 2BN
United Kingdom

Date	Reference Number	Action
04 May 2014	10145035	Administrative update to certificate format. Addition of alternative manufacturing site, Smith & Nephew Medical (Suzhou) Ltd, China for product codes 66003650, 7457 and 66003661. Increased capacity of mass mixing process at Smith & Nephew Medical (Suzhou) Ltd, China. Removal of product codes 7456G, 7457G and 7461G.
15 May 2014	10139742 10146201	Extension of shelf life (assigning shelf life at the point the product is packaged). Addition of alternative manufacturing site, Smith & Nephew (Suzhou) Ltd China for product codes 7456, 7461, 66007505.
15 December 2015	10159049	Certificate renewal.
20 November 2018	8903083	Addition of sterilisation site Suzhou CNNC Huadong. Administrative change to product table.
27 February 2019	7779270	Traceable to NB 0086.
Current	9767541	Certificate renewal. Correction to model/type information in supplementary information table. Removal of leg ulcers as an indication. Addition of EU Rep information to product labelling.

First Issued: **1995-12-21** Date: **2020-01-30** Expiry Date: **2024-05-26**

...making excellence a habit.™