

Smith & Nephew Medical Ltd.
101 Hessle Road
Hull, HU3 2BN
England

T + 44 (0) 1482 225181
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www.smith-nephew.com



EUROPEAN DECLARATION OF CONFORMITY

This Declaration confirms that the product listed below meets the Essential Requirements set out in Annex I of the Council Directive 93/42/EEC (as amended).

Manufacturer's Name:	Smith & Nephew Medical Limited
Business Address:	101 Hessle Road, Hull, HU3 2BN, United Kingdom.
Authorised Representative:	Smith & Nephew Operations B.V Bloemlaan 2, 2132 NP Hoofddorp, Netherlands
Medical Devices:	PICO 7 Single Use Negative Pressure Wound Therapy System
Classification:	Class IIb Sterile
GMDN Code and Term:	58202: Negative-pressure wound therapy system, electric, single-use
Scope of Application:	All batches supplied to which the Declaration of Conformity Procedure has been applied.
Declaration:	Conformity of the product has been assessed in accordance with Annex II of the Directive. A dossier of technical documentation, as required by the Directive is available. The product listed is designed, manufactured and tested in accordance with the information set out in the dossier.
Verification Certificate(s):	EC Certificate No. CE 00356 Full Quality Assurance. Notified Body No. 2797 (British Standards Institution) British Standards Institution. Certificate No. MD 76718 Quality Management System (BS EN ISO 13485) British Standards Institution. Certificate No. FM 24676 Quality Management System (BS EN ISO 9001)
Standards Applied:	BS EN ISO 9001:2015 BS EN ISO 13485:2016 + A1:2021 BS EN ISO 14971:2019 + A11:2021 BS EN 556-1:2001 BS EN ISO 11135:2014 +A1:2019 BS EN ISO 11737-1:2018+A1:2021 BS EN ISO 11737-2:2020

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- BS EN ISO 14644-1:2015
- BS EN ISO 11607-1: 2020
- BS EN ISO 11607-2: 2020
- BS EN ISO 780:2015
- BS EN ISO 20417:2021
- BS EN ISO 10993-1: 2020
- BS EN ISO 10993-2:2006
- BS EN ISO 10993-3:2014
- BS EN ISO 10993-5:2009
- BS EN ISO 10993-7:2008+A1:2022
- BS EN ISO 10993-10:2023
- BS EN ISO 10993-11:2018
- BS EN ISO 10993-12:2021
- BS EN ISO 10993-18:2020
- BS EN ISO 10993-23:2021
- BS EN 13726-1:2002/AC:2003
- BS EN 13726-2: 2002
- BS EN 13726-3: 2003
- BS EN 13726-4:2003
- BS EN ISO 15223-1:2021
- Restriction of Hazardous Substances (RoHS) Directive – 2011/65/EU
- ISTA 2A:2011
- IEC 60601-1: 2005+AMD1:2012
- IEC 60601-1-2:2014 4th Edition
- IEC 60601-1-6:2010+A1:2013 3.1 Edition
- IEC 60601-1-11: 2015 1st Edition
- IEC 62366: 2015+AMD1:2020
- BS EN IEC 63000:2018
- IEC 62304:2006+AMD1:2015 CSV
- WEEE Directive 2012/19/EU
- EU battery regulation EU2023/1542

Product Codes:

Code	Size
66802002	10cm x 20cm
66802003	10cm x 30cm
66802004	10cm x 40cm
66802005	15cm x 15cm
66802006	15cm x 20cm
66802007	15cm x 30cm
66802008	20cm x 20cm
66802009	25cm x 25cm
66802000	15cm x 20cm
66802001	20cm x 25cm
66802012	10cm x 20cm
66802013	10cm x 30cm
66802014	10cm x 40cm
66802015	15cm x 15cm
66802016	15cm x 20cm
66802017	15cm x 30cm
66802018	20cm x 20cm
66802019	25cm x 25cm

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66802010	15cm x 20cm
66802011	20cm x 25cm
66802022	10cm x 20cm
66802023	10cm x 30cm
66802024	10cm x 40cm
66802025	15cm x 15cm
66802026	15cm x 20cm
66802027	15cm x 30cm
66802028	20cm x 20cm
66802029	25cm x 25cm
66802020	15cm x 20cm
66802021	20cm x 25cm

Authorised Signatory:

Name:

Sam Greenhalgh

Position:

Regulatory Affairs Director

Signed by:
Sam Greenhalgh
Signer Name: Sam Greenhalgh
Signing Reason: I approve this document
Signing Time: 03-Mar-2026 | 11:08:10 GMT
1C73ED93193D48889F66F071859C80BC

Signed:

03-Mar-2026 | 11:08:31 GMT

Dated:

Certificate Reference:

HU/142 issue 020