

Smith & Nephew Medical Limited

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Manufacturer's Confirmation in regard to Regulation 2023/607

with respect to the certificates issued under Council Directive 93/42/EEC on medical devices ("MDD"), ("Directive Certificates") and their validity per Article 120(2) of Regulation (EU) 2017/745 on medical devices as amended by Regulation 2023/607 of 20 March 2023 ("MDR") and with respect to the Devices' and its Manufacturer's compliance with the conditions to continued placing on the market as per Article 120(3) of the MDR

Manufacturer name	Smith & Nephew Medical Ltd.
Manufacturer address	101 Hessle Road Hull HU3 2BN United Kingdom
Manufacturer EUDAMED SRN	GB-MF-000017580
Notified Body name	BSI
Notified Body number	2797

This is confirmation that the devices listed below meet following conditions for extension of certificates issued under Council Directive Council Directive 93/42/EEC on medical devices (MDD) as stated in Regulation (EU) 2023/607 amending Regulation (EU) 2017/745 on medical devices

- The certificate(s) covering the listed devices was valid on the 26 May 2021.
- The device(s) continue to comply with Directive 93/42/EEC (MDD)
- There are no significant changes in the design and intended purpose since 26 May 2021.
- The device(s) do not present unacceptable risks to health or safety of patients, users or other persons, or to other aspects of the protection of public health
- A quality management system in accordance with Article 10(9), Regulation (EU) 2017/745 (MDR) has been put in place by the manufacturer no later than 26 May 2024.
- A formal application to the notified body in accordance with Section 4.3, first subparagraph, of Annex VII, Regulation (EU) 2017/745 (MDR) for conformity assessment has been made for the device(s) listed and a signed written agreement is in place in accordance with Section 4.3, second subparagraph, of Annex VII, Regulation (EU) 2017/745 (MDR). This was completed prior to the expiry of the certificate
- Post-market surveillance, market surveillance, vigilance, registration of economic operators in accordance with Regulation (EU) 2017/745 (MDR) is in place for the device(s) listed.

Signature:

DocuSigned by:

Signer Name: Andrew Daghli
Signing Reason: I approve this document
Signing Time: 15-May-2024 | 10:05:38 BST
303C90DE917A4F32AA0ABF5C275816BC

Date: 15-May-2024 | 10:05:42 BST

Print name: Andrew Daghli

Title/position: Regulatory Affairs Manager

Schedule of devices

Catalog Item	Description	Certificate number	Expiry date on the certificate	Extended expiry date
66802000	PICO 7 Multisite Small 15cm x 20cm	CE 00356	26 th May 2024	31st Dec 2028
66802001	PICO 7 MULTISITE LARGE 20CM X 25CM	CE 00356	26 th May 2024	31st Dec 2028
66802002	PICO 7 10cm x 20cm	CE 00356	26 th May 2024	31st Dec 2028
66802003	PICO 7 10cm x 30cm	CE 00356	26 th May 2024	31st Dec 2028
66802004	PICO 7 10cm x 40cm	CE 00356	26 th May 2024	31st Dec 2028
66802005	PICO 7 15cm x 15cm	CE 00356	26 th May 2024	31st Dec 2028
66802006	PICO 7 15cm x 20cm	CE 00356	26 th May 2024	31st Dec 2028
66802007	PICO 7 15cm x 30cm	CE 00356	26 th May 2024	31st Dec 2028
66802008	PICO 7 20cm x 20cm	CE 00356	26 th May 2024	31st Dec 2028
66802009	PICO 7 25cm x 25cm	CE 00356	26 th May 2024	31st Dec 2028
66802010	PICO 7 Single Drsg M/Site Small 15x20cm	CE 00356	26 th May 2024	31st Dec 2028
66802011	PICO 7 Single Drsg M/Site Large 20x25cm	CE 00356	26 th May 2024	31st Dec 2028
66802012	PICO 7 Single Dressing 10cm x 20cm	CE 00356	26 th May 2024	31st Dec 2028
66802013	PICO 7 Single Dressing 10cm x 30cm	CE 00356	26 th May 2024	31st Dec 2028
66802014	PICO 7 Single Dressing 10cm x 40cm	CE 00356	26 th May 2024	31st Dec 2028
66802015	PICO 7 Single Dressing 15cm x 15cm	CE 00356	26 th May 2024	31st Dec 2028
66802016	PICO 7 Single Dressing 15cm x 20cm	CE 00356	26 th May 2024	31st Dec 2028
66802017	PICO 7 Single Dressing 15cm x 30cm	CE 00356	26 th May 2024	31st Dec 2028
66802018	PICO 7 Single Dressing 20cm x 20cm	CE 00356	26 th May 2024	31st Dec 2028
66802019	PICO 7 Single Dressing 25cm x 25cm	CE 00356	26 th May 2024	31st Dec 2028
66802020	PICO MULTISITE SMALL DRESSING - 5 PACK	CE 00356	26 th May 2024	31st Dec 2028
66802021	PICO MULTISITE LARGE DRESSING - 5 PACK	CE 00356	26 th May 2024	31st Dec 2028
66802022	PICO 10cm x 20cm DRESSING - 5 PACK	CE 00356	26 th May 2024	31st Dec 2028
66802023	PICO 10cm x 30cm DRESSING - 5 PACK	CE 00356	26 th May 2024	31st Dec 2028
66802024	PICO 10cm x 40cm Dressing - 5 Pack	CE 00356	26 th May 2024	31st Dec 2028
66802025	PICO 15cm x 15cm Dressing - 5 Pack	CE 00356	26 th May 2024	31st Dec 2028
66802026	PICO 15cm x 20cm Dressing - 5 Pack	CE 00356	26 th May 2024	31st Dec 2028
66802027	PICO 15cm x 30cm Dressing - 5 Pack	CE 00356	26 th May 2024	31st Dec 2028
66802028	PICO 20cm x 20cm Dressing - 5 Pack	CE 00356	26 th May 2024	31st Dec 2028

Catalog Item	Description	Certificate number	Expiry date on the certificate	Extended expiry date
66802029	PICO 25cm x 25cm Dressing - 5 Pack	CE 00356	26 th May 2024	31st Dec 2028
66802031	PICO 7Y SINGLE USE NPWT SYSTEM	CE 00356	26 th May 2024	31st Dec 2028
66802040	PICO 14 MULTISITE SMALL 15x20cm CTN1	CE 00356	26 th May 2024	31st Dec 2028
66802041	PICO 14 MULTISITE LARGE 20x25cm CTN1	CE 00356	26 th May 2024	31st Dec 2028
66802042	PICO 14 10x20cm CTN1	CE 00356	26 th May 2024	31st Dec 2028
66802043	PICO 14 10x30cm CTN1	CE 00356	26 th May 2024	31st Dec 2028
66802044	PICO 14 10x40cm CTN1	CE 00356	26 th May 2024	31st Dec 2028
66802045	PICO 14 15x15cm CTN1	CE 00356	26 th May 2024	31st Dec 2028
66802046	PICO 14 15x20cm CTN1	CE 00356	26 th May 2024	31st Dec 2028
66802047	PICO 14 15x30cm CTN1	CE 00356	26 th May 2024	31st Dec 2028
66802048	PICO 14 20x20cm CTN1	CE 00356	26 th May 2024	31st Dec 2028
66802049	PICO 14 25x25cm CTN1	CE 00356	26 th May 2024	31st Dec 2028
66771359	RENASYS Dressing Kit with Soft Port Small Kit	CE 00356	26 th May 2024	31st Dec 2028
66771360	RENASYS Dressing Kit with Soft Port Medium Kit	CE 00356	26 th May 2024	31st Dec 2028
66771361	RENASYS Dressing Kit with Soft Port Large Kit	CE 00356	26 th May 2024	31st Dec 2028
66771362	RENASYS Dressing Kit with Soft Port X-Large Kit	CE 00356	26 th May 2024	31st Dec 2028
02436	Dressing Non-Adherent 3"x3"	CE 00356	26 th May 2024	31st Dec 2028
02437	Dressing Non-Adherent 3"x8"	CE 00356	26 th May 2024	31st Dec 2028
66800980	RENASYS AB Abdominal Dressing Kit with Soft Port	CE 00356	26 th May 2024	31st Dec 2028
66800794	RENASYS-F Foam Dressing Kit with Soft Port Small Kit (10 x 8 x 3cm / 3.9 x 3.1 x 1.2in)	CE 00356	26 th May 2024	31st Dec 2028
66800795	RENASYS-F Foam Dressing Kit with Soft Port Medium Kit (20 x 12.5 x 3cm / 7.9 x 4.9 x 1.2in)	CE 00356	26 th May 2024	31st Dec 2028
66800796	RENASYS-F Foam Dressing Kit with Soft Port Large Kit (25 x 15 x 3cm / 9.8 x 5.9 x 1.2in)	CE 00356	26 th May 2024	31st Dec 2028
66800797	RENASYS-F Foam Dressing Kit with Soft Port X-Large Kit (48 x 41 x 1.5cm / 18.9 x 16.1 x 0.6in)	CE 00356	26 th May 2024	31st Dec 2028
66801253	RENASYS 15Fr Channel Drain Accessory Kit	CE 00356	26 th May 2024	31st Dec 2028
66801252	RENASYS 10mm Flat Drain Accessory Kit	CE 00356	26 th May 2024	31st Dec 2028

Catalog Item	Description	Certificate number	Expiry date on the certificate	Extended expiry date
66801251	RENASYS 10Fr Round Drain Accessory Kit	CE 00356	26 th May 2024	31st Dec 2028
66801254	RENASYS 19Fr Round Drain Accessory Kit	CE 00356	26 th May 2024	31st Dec 2028
66800799	RENASYS Soft Port	CE 00356	26 th May 2024	31st Dec 2028
66800853	RENASYS X-Large Transparent Film Dressing Kit	CE 00356	26 th May 2024	31st Dec 2028
66802134	RENASYS TOUCH Negative Pressure Wound Therapy	CE 00356	26 th May 2024	31st Dec 2028