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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:
sam greenhalgh
Signer Name: sam greenhalgh
Signing Reason: I approve this document
Signing Time: 29-Apr-2024 | 14:45:40 BST
1C73ED93193D48889F66F071859C80BC

Date: 29-Apr-2024

Print name: Sam Greenhalgh

Title/position: Regulatory Affairs Director

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Schedule of devices

Catalog Item	Description	Certificate number	Expiry date on the certificate	Extended expiry date
66003650	BACTIGRAS 10cm x 10cm	CE 00356/CE 01105	26th May 2024	31st Dec 2027
66003661	BACTIGRAS 10cm x 40cm	CE 00356/CE 01105	26th May 2024	31st Dec 2027
7456	BACTIGRAS 5cm x 5cm	CE 00356/CE 01105	26th May 2024	31st Dec 2027
7457	BACTIGRAS 10cm x 10cm	CE 00356/CE 01105	26th May 2024	31st Dec 2027
7461	BACTIGRAS 15cm x 20cm	CE 00356/CE 01105	26th May 2024	31st Dec 2027
66007505	BACTIGRAS on a Roll (BOAR) 15cm x 1m	CE 00356/CE 01105	26th May 2024	31st Dec 2027
66001290	Iodosorb Dressing 5×5g	CE 00356/ CE511078	26th May 2024	31st Dec 2027
66001291	Iodosorb Dressing 3×10g	CE 00356/ CE511078	26th May 2024	31st Dec 2027
66001292	Iodosorb Dressing 5×10g	CE 00356/ CE511078	26th May 2024	31st Dec 2027
66001293	Iodosorb Dressing 2×17g	CE 00356/ CE511078	26th May 2024	31st Dec 2027
66001297	Iodosorb Ointment 2×20g	CE 00356/ CE511078	26th May 2024	31st Dec 2027
66001298	Iodosorb Ointment 4×10g	CE 00356/ CE511078	26th May 2024	31st Dec 2027
66001299	Iodosorb Ointment 1×40g	CE 00356/ CE511078	26th May 2024	31st Dec 2027
66001286	Iodosorb Powder 7×3g	CE 00356/ CE511078	26th May 2024	31st Dec 2027
66001295	IODOSORB Salbe 2×20g	CE 00356/ CE511078	26th May 2024	31st Dec 2027
66001296	IODOSORB Salbe 1×40g	CE 00356/ CE511078	26th May 2024	31st Dec 2027
66001301	IODOFLEX 5×5g	CE 00356/ CE511078	26th May 2024	31st Dec 2027
66001302	IODOFLEX 3×10g	CE 00356/ CE511078	26th May 2024	31st Dec 2027
66001303	IODOFLEX 2×17g	CE 00356/ CE511078	26th May 2024	31st Dec 2027
66000809	ACTICOAT 7 (5cm x 5cm /2in. x 2in.)	CE00356/CE 90692	26th May 2024	31st Dec 2027
66000796	ACTICOAT 7 (10cm x 12.5cm / 4in. x 5in.)	CE00356/CE 90692	26th May 2024	31st Dec 2027
66000797	ACTICOAT 7 (15cm x 15cm /6in. x 6in.)	CE00356/CE 90692	26th May 2024	31st Dec 2027
66800395	ACTICOAT FLEX 7 (5cm x 5cm)	CE00356/CE 544419	26th May 2024	31st Dec 2027
66800397	ACTICOAT FLEX 7 (10cm x 12.5cm)	CE00356/CE 544419	26th May 2024	31st Dec 2027
66800400	ACTICOAT FLEX 7 (20cm x 40cm)	CE00356/CE 544419	26th May 2024	31st Dec 2027
66800401	ACTICOAT FLEX 7 (40cm x 40cm)	CE00356/CE 544419	26th May 2024	31st Dec 2027
66800420	ACTICOAT FLEX 7 (15cm x 15cm)	CE00356/CE 544419	26th May 2024	31st Dec 2027
66800545	ACTICOAT FLEX 7 (2.5cm x 60cm)	CE00356/CE 544419	26th May 2024	31st Dec 2027
66800396	ACTICOAT FLEX 3 (5cm x 5cm)	CE00356/CE 547893	26th May 2024	31st Dec 2027
66800398	ACTICOAT FLEX 3 (10cm x 10cm)	CE00356/CE 547893	26th May 2024	31st Dec 2027
66800399	ACTICOAT FLEX 3 (10cm x 10cm)	CE00356/CE 547893	26th May 2024	31st Dec 2027

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Catalog Item	Description	Certificate number	Expiry date on the certificate	Extended expiry date
66800409	ACTICOAT FLEX 3 (10cm x 20cm)	CE00356/CE 547893	26th May 2024	31st Dec 2027
66800419	ACTICOAT FLEX 3 (20cm x 40cm)	CE00356/CE 547893	26th May 2024	31st Dec 2027
66800432	ACTICOAT FLEX 3 (40cm x 40cm)	CE00356/CE 547893	26th May 2024	31st Dec 2027
66800435	ACTICOAT FLEX 3 (10cm x 120cm)	CE00356/CE 547893	26th May 2024	31st Dec 2027
66801290	ACTICOAT FLEX 3 (4cm x 15cm)	CE00356/CE 547893	26th May 2024	31st Dec 2027
66801291	ACTICOAT FLEX 3 (4cm x 25cm)	CE00356/CE 547893	26th May 2024	31st Dec 2027
66801292	ACTICOAT FLEX 3 (4cm x 35cm)	CE00356/CE 547893	26th May 2024	31st Dec 2027
66801293	ACTICOAT FLEX 3 (20cm x 20cm)	CE00356/CE 547893	26th May 2024	31st Dec 2027