



EC DECLARATION OF CONFORMITY

IN RELATION TO PHMB ANTIMICROBIAL FOAM WOUND DRESSING (DESIGN DOSSIER 05)

Advanced Medical Solutions Ltd. (Premier Park, 33 Road One, Winsford Industrial Estate, Winsford, Cheshire, CW7 3RT, United Kingdom) declares that the Class III medical devices manufactured by Advanced Medical Solutions and described hereafter as:

Product Name	Size [cm]	Catalogue Number [REF]
Suprasorb® P + PHMB Antimicrobial Foam Dressing (non-adhesive)	5 x 5	34 540
	7.5 x 7.5	34 541
	7.5 x 7.5	34 546
	10 x 10	34 542
	10 x 10	34 547
	10 x 20	34 543
	15 x 15	34 544
	20 x 20	34 545

GMDN Code: 48124 – Exudate-absorbent dressing, non-gel, antimicrobial.

are in conformity with the essential requirements and provisions of Council Directive 93/42/EEC (Medical Devices Directive) amended by Directive 2007/47/EC, as transposed into UK Regulations (Statutory Instrument 2002 No. 618 and Statutory Instrument 2012 No. 1426) subject to and in conformity with the applicable provisions of Annex II (including Section 4), Full Quality Assurance Certificate (CE 01699) and EC Design Examination certificate (CE 600773), under the supervision of our Notified Body the British Standards Institution (2797).

Authorised Representative: Advanced Medical Solutions B.V.,
Munnikenheiweg 35, 4879 NE Etten-Leur, Netherlands.

Standards Applied: Refer to reference Design Dossier 05 (DD05)

Issued in Winsford, UK.

Adam Gregory
Regulatory Affairs Manager

15 JULY 2020

Date

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