

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

T + 44 (0) 1482 225181
F + 44 (0) 1482 328326
www.smith-nephew.com

Smith+Nephew

EUROPEAN DECLARATION OF CONFORMITY ¹

Declaration confirms that the product listed below meets: Regulation 2017/745 and is issued under the sole responsibility of Smith & Nephew Medical Limited².

Manufacturer's Name³	Smith & Nephew Medical Limited
Business Address⁴	101 Hessle Road, Hull, HU3 2BN, United Kingdom
Single Registration Number (SRN) ⁵	GB-MF-000017580
European Authorised Representative⁶	Smith & Nephew Operations B.V.
Business Address⁷	Bloemlaan 2, 2132 NP Hoofddorp, Netherlands
Product Name⁸:	ALGISITE M
Intended Use⁹	To treat pressure ulcers and venous leg ulcers, with moderate to heavy exudate. To facilitate the control of minor bleeding.
Conformity Assessment Procedure (Annex)¹⁰	IX
Notified Body Name¹¹	BSI Group The Netherlands B. V
Notified Body Number¹²	No. 2797
Verification Certificate(s)¹³	732832

Signed on behalf of Smith & Nephew Medical Limited¹⁴	
Signature¹⁵	 DocuSigned by: Sam Greenhalgh Signer Name: Sam Greenhalgh Signing Reason: I approve this document Signing Time: 06-Apr-2023 11:16:49 BST 1C73ED93193D48889F66F071859C80BC
Name¹⁶	Sam Greenhalgh
Position¹⁷	Regulatory Affairs Director
Date¹⁸	06 April 2023
Location¹⁹	Hull
Declaration of Conformity Reference²⁰	DOC-WMTF-41/V1

Registered No. 605496 in England and Wales, registered Office: PO Box 81, 101 Hessle Road, Hull, HU3 2BN, England
Smith & Nephew Medical Limited, acting as agent for T.J. Smith and Nephew, Limited.

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Product Schedule²¹			
Product Code / Catalogue Number²²	Product Description or Product Variant²³	Risk Classification²⁴	Basic UDI²⁵
66000519	ALGISITE M 5cm×5cm	IIb	5000223SN000132R6
66000520	ALGSIITE M 10cm×10cm	IIb	5000223SN000132R6
66000521	ALGISITE M 15cm×20cm	IIb	5000223SN000132R6
66000522	ALGISITE M 2cm×30cm	IIb	5000223SN000132R6
66000718	ALGISITE M 10cm×10cm	IIb	5000223SN000132R6
66000719	ALGISITE M 15cm×15cm	IIb	5000223SN000132R6

Standards / Common Specification(s)²⁶:
EN ISO 780:2015
EN ISO 13485: 2016+A11: 2021
EN ISO 15223-1:2021
EN ISO 14971:2019+A11: 2021
EN ISO 10993-1:2020
EN ISO 10993-3:2014
EN ISO 10993-5:2009
EN ISO 10093-10:2021
EN ISO 10993-18:2020
EN ISO 20147: 2021
IEC 62366-1: 2015/AMD 1:2020
EN 556-1:2001/AC:2006
EN ISO 14644-1:2015
ISO 11607-1:2019
EN ISO 11607-2:2020
EN ISO 11137-1:2015+A2:2019
EN ISO 11137-2:2015
EN ISO 11737-1:2018+ A1: 2021
EN ISO 11737-2:2020

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Intended Use European Language Translations²⁷:			
Language²⁸		Code	Intended Use
EN	Local		
Bulgarian	български език	BG	За лечение на декубитуси и венозни язви на краката, с умерен до тежък ексудат. За улесняване на контрола на леко кървене.
Croatian	Hrvatski	HR	Za liječenje dekubitalnih ulkusa i venskih ulkusa noge s umjerenim do jakim eksudatom. Za lakše kontroliranje manjeg krvarenja.
Czech	Český Jazyk	CZ	K léčbě dekubitů a bércových vředů se střední až silnou exsudací. K usnadnění kontroly slabého krvácení.
Danish	Dansk	DK	Til behandling af moderat til kraftigt væskende tryksår og venøse bensår. Medvirker til kontrol af mindre blødning
Dutch	Nederlands	NL	Voor de behandeling van decubitus en veneuze beenulcera, met matig tot zwaar exsudaat. Om de controle van kleine bloedingen te vergemakkelijken.
Estonian	Eesti	EE	Mõõduka kuni rohke eksudaadiga lamatishaavandite ja venoosete jalahaavandite raviks. Väiksema verejooksu kontrolli all hoidmise hõlbustamiseks.
Finnish	Suomi	FI	Painehaavojen ja laskimoperäisten säärihaavojen hoitoon, kohtalaisella tai runsaalla tulehdusnesteellä. Pienten verenvuotojen hallinnan helpottamiseksi.
French	Français	FR	Pour traiter les escarres dues à la pression et les ulcères veineux de jambe, avec un exsudat modéré à important. Pour faciliter le contrôle des saignements mineurs.
German	Deutsch	DE	Zur Behandlung von Dekubitus und Ulcus cruris mit mäßiger bis starker Exsudation. Zur Erleichterung der Kontrolle von kleineren Blutungen.
Greek	Ελληνικά	GR	Για την αντιμετώπιση ελκών εκ πίεσης και φλεβικών ελκών των ποδιών, με μέτρια έως έντονη εξιδρώση. Για τη διευκόλυνση του ελέγχου αιμορραγίας ελάσσονος σημασίας.
Hungarian	Magyar	HU	A közepesen-erősen váladékozó felfekvések és vénás lábszárfekélyek kezelése. A kisebb vérzés kontrollálásának elősegítése.
Italian	Italiano	IT	Per il trattamento di ulcere da decubito e ulcere dell'arto inferiore con abbondante o moderata quantità di essudato. Per facilitare il controllo dei sanguinamenti minori.
Latvian	Latviešu	LV	Spiediena čūlu un kājas vēnu čūlu ārstēšanai, ar mērenu līdz bagātīgu eksudātu. Lai atvieglotu nelielas asiņošanas kontroli.
Lithuanian	Lietuvių	LT	Praguloms ir veninėms kojų opoms gydyti su vidutiniu ar dideliu kiekiu eksudato. Palengvinti nedidelio kraujavimo valdymą.

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Polish	Polski	PL	Leczenie odleżyn i owrzodzeń żyłakowych podudzi z wysiękiem umiarkowanym do obfitego. Ułatwienie tamowania drobnych krwawień.
Portuguese	Português	PT	Para tratar úlceras de pressão e úlceras de perna venosas, com exsudado moderado a pesado. Para facilitar o controlo de hemorragias menores.
Romanian	Română	RO	Pentru a trata escarele de decubit și ulcerele venoase ale piciorului cu exsudat de la moderat la abundent. Pentru facilitarea controlului sângerărilor minore.
Slovak	Slovenčina	SK	Na liečbu preležanín a žilových vredov na nohách so stredne silným až silným exsudátom. Na uľahčenie kontroly menšieho krvácania.
Slovenian	Slovenščina	SI	Za zdravljenje preležanin in nožnih venskih razjed z zmernim do močnim izcedkom. Za lažji nadzor manjših krvavitev.
Spanish	Español	ES	Está indicado en el tratamiento de úlceras por presión y úlceras venosas de la pierna, con exudado de moderado a alto. También está indicado para facilitar el control de la hemorragia leve.
Swedish	Svenska	SE	För att behandla trycksår och venösa bensår med måttligt till kraftigt exsudat. För att underlätta kontrollen på mindre blödningar.
Norwegian	Norsk	NO	Til behandling av moderat/kraftig væskende trykksår og venøse leggsår. Hjelper til å stoppe mindre blødninger.
Turkish	Türkçe	TR	Orta düzey ile aşırı düzeyde eksüdanın mevcut olduğu bası ülserlerini ve venöz bacak ülserlerini tedavi etmek için. Ufak kanamanın kontrol edilmesini kolaylaştırmak için.

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Appendices - European Language Term Translations:

Appendix no.	Language (EN)	Language (Local)	Country Code
Appendix 1	Bulgarian	български език	BG
Appendix 2	Croatian	Hrvatski	HR
Appendix 3	Czech	Český Jazyk	CZ
Appendix 4	Danish	Dansk	DK
Appendix 5	Dutch	Nederlands	NL
Appendix 6	Estonian	Eesti	EE
Appendix 7	Finnish	Suomi	FI
Appendix 8	French	Français	FR
Appendix 9	German	Deutsch	DE
Appendix 10	Greek	Ελληνικά	GR
Appendix 11	Hungarian	Magyar	HU
Appendix 12	Italian	Italiano	IT
Appendix 13	Latvian	Latviešu	LV
Appendix 14	Lithuanian	Lietuvių	LT
Appendix 15	Polish	Polski	PL
Appendix 16	Portuguese	Português	PT
Appendix 17	Romanian	Română	RO
Appendix 18	Slovak	Slovenčina	SK
Appendix 19	Slovenian	Slovenščina	SI
Appendix 20	Spanish	Español	ES
Appendix 21	Swedish	Svenska	SE
Appendix 22	Norwegian	Norsk	NO
Appendix 23	Turkish	Türkçe	TR

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Regulatory Affairs Director

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