

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: Regulations 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:	ALLEVYN THIN
Intended Use⁹	ALLEVYN THIN Dressings are indicated for: • management of superficial wounds with light exudate including minor burns, and abrasions • pressure ulcers • leg ulcers • surgical wounds • skin graft donor sites. 66045124 ALLEVYN THIN 15cm x 15cm ALLEVYN THIN Dressings are indicated for the treatment of pressure ulcers and venous leg ulcers that heal by secondary intention with light exudate.
Conformity Assessment Procedure (Annex)¹⁰	Annex IX Chapter I & III
Notified Body Name¹¹	BSI Group The Netherlands B.V
Notified Body Number¹²	No. 2797
Verification Certificate(s)¹³	MDR 732832

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

Signed on behalf of Smith & Nephew Medical Limited ¹⁴	
Signature¹⁵	DocuSigned by:  Signer Name: Andrew Daglish Signing Reason: I approve this document Signing Time: 14-Dec-2023 16:06:42 GMT 303C90DE917A4F32AA0ABF5C275816BC
Name¹⁶	<u>Andrew Daglish</u>
Position¹⁷	<u>Senior Regulatory Affairs Specialist</u>
Date¹⁸	<u>14th December 2023</u>
Location¹⁹	<u>Hull, UK</u>
Declaration of Conformity Reference²⁰	DOC-WMTF-039/V1

Product Schedule ²¹			
Product Code / Catalogue Number ²²	Product Description or Product Variant ²³	Risk Classification ²⁴	Basic UDI ²⁵
66012615	ALLEVYN THIN 5cm x 6cm	Class IIb	5000223SN000130R2
66012616	ALLEVYN THIN 10cm x 10cm	Class IIb	5000223SN000130R2
66045124	ALLEVYN THIN 15cm x 15cm	Class IIb	5000223SN000130R2
66047576	ALLEVYN THIN 5cm x 6cm	Class IIb	5000223SN000130R2
66047578	ALLEVYN THIN 10cm x 10cm	Class IIb	5000223SN000130R2
66047579	ALLEVYN THIN 15cm x 20cm	Class IIb	5000223SN000130R2

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 10993-10:2023
EN ISO 10993-18:2020
EN ISO 10993-17:2009
EN ISO 10993-23:2021
EN ISO 20147: 2021
IEC 62366-1: 2015/AMD 1:2020
EN 556-1:2001/AC:2006

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.

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

EN ISO 11137-1:2015+ A2: 2019
EN ISO 11137-2:2015
EN ISO 14644-1:2015
EN ISO 14644-2:2015
EN ISO 11607-1:2019
EN ISO 11607-2:2020
EN ISO 11737-1:2018+ A1: 2021
EN ISO 11737-2:2020
EN ISO 14644-1:2015
EN ISO 14644-2:2015
EN ISO 11607-1:2019
EN ISO 11607-2:2020
EN ISO 11737-1:2018+ A1: 2021
EN ISO 11737-2:2020
EN 13726-1:2002
EN 13726-2:2002
EN 13726-3:2003
EN 13726-4:2003

Intended Use European Language Translations ²⁷ :			
Language ²⁸		Code	Intended Use
EN	Local		
Croatian	Hrvatski	HR	Obloge ALLEVYN THIN indicirane su za: liječenje površinskih rana s laganim eksudatom, uključujući manje opekline i abrazije; dekubitalne ulkuse; ulkuse na nogama; kirurške rane; mjesta transplantata kože. 66045124 ALLEVYN THIN: Obloge ALLEVYN THIN indicirane su za liječenje dekubitalnih ulkusa i venskih ulkusa na nogama koji zacjeljuju sekundarnim cijeljenjem uz blag eksudat.
Czech	Český Jazyk	CZ	Krytí ALLEVYN THIN je indikováno pro: Ošetření povrchových ran s malým množstvím exsudátu, včetně lehčích popálenin a abrazí; Proleženiny; Bércové vředy; Operační rány; Dárcovská místa kožních štěpů. 66045124 ALLEVYN THIN: Indikace Krytí ALLEVYN THIN je indikováno k léčbě proleženin a žilních bérkových vředů, které se hojí sekundárně s malým množstvím exsudátu.
Danish	Dansk	DK	ALLEVYN THIN-bandager er indiceret til: Håndtering af overfladiske let ekssuderende sår herunder mindre forbrændinger og slidsår; Tryksår; Bensår; Operationssår; Donorsteder for hudgrafter. 66045124 ALLEVYN THIN: ALLEVYN THIN-bandager er indiceret til behandling af tryksår og venøse bensår, der heler ved sekundær intention med let ekssudat.

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.

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

Dutch	Nederlands	NL	ALLEVYN THIN-verbanden zijn geïndiceerd voor: De verzorging van oppervlakkige, licht exsuderende wonden, waaronder lichte brandwonden en ontvellingen; Decubituswonden; Beenulcera; Operatiewonden; Donorplaatsen voor huidtransplantaten. 66045124 ALLEVYN THIN: ALLEVYN THIN-verbanden zijn geïndiceerd voor de behandeling van decubituswonden en veneuze beenulcera bij een verstoord genezingsproces met licht exsudaat.
Finnish	Suomi	FI	ALLEVYN THIN -sidoksia käytetään seuraavien hoitoon: pinnalliset, vähän erittävät haavat, kuten lievät palovammat ja hiertymät; painehaavat; säärihaavat; kirurgiset haavat; ihonsiirteiden luovutuskohdat. 66045124 ALLEVYN THIN: ALLEVYN THIN -sidokset on tarkoitettu vähän erittävien painehaavojen ja laskimoperäisten säärihaavojen toissijaiseen hoitoon.
French	Français	FR	Les pansements ALLEVYN THIN sont indiqués pour : La prise en charge des plaies superficielles avec peu d'exsudat, y compris les brûlures légères et les abrasions. Escarres; Ulcères de jambe; Plaies chirurgicales; Sites donneurs de greffe de peau. 66045124 ALLEVYN THIN: ALLEVYN THIN Les pansements ALLEVYN THIN sont indiqués pour le traitement des escarres et des ulcères de jambe veineux qui cicatrisent par deuxième intention avec un léger exsudat.
German	Deutsch	DE	ALLEVYN THIN Verbände sind für folgende Verwendungen indiziert: Versorgung von oberflächlichen Wunden mit wenig Exsudat, einschließlich leichte Verbrennungen und Schürfwunden, Druckgeschwüre, Beingeschwüre, Operationswunden, Entnahmestellen zur Hauttransplantation. 66045124 ALLEVYN THIN: für die Behandlung von Druckgeschwüren und venösen Beingeschwüren indiziert, die durch sekundäre Wundheilung mit wenig Exsudat heilen.
Italian	Italiano	IT	Le medicazioni ALLEVYN THIN sono indicate nei casi seguenti: gestione di ferite superficiali con lieve presenza di essudato, comprese ustioni superficiali e abrasioni; ulcere da pressione; ulcere degli arti inferiori; ferite chirurgiche; siti donatori di innesti cutanei. 66045124 ALLEVYN THIN: Le medicazioni ALLEVYN THIN sono indicate per il trattamento di ulcere da pressione e ulcere venose degli arti inferiori che guariscono per seconda intenzione con lieve presenza di essudato.
Latvian	Latviešu	LV	ALLEVYN THIN pārsēji ir indicēti tālākminētajos

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

			gadījumos. Virspusēju brūču ar vieglu eksudātu, tostarp nelielu apdegumu un noberzumu, ārstēšana; Izgulējumi; Kāju čūlas; Ķirurģiskas brūces; Ādas pārstādīšanas donorvietas. 66045124 ALLEVYN THIN: ALLEVYN THIN pārsēji ir indicēti izgulējumu un kāju vēnu čūlu ārstēšanai, brūcei dzīstot no apakšas ar vieglu eksudātu.
Polish	Polski	PL	Opatrunki ALLEVYN THIN są przeznaczone do: Zaopatrzenia ran powierzchniowych o lekkim wysięku, takich jak drobne oparzenia i otarcia; Odleżyny; Owrzodzenia kończyn dolnych; Rany pooperacyjne; Miejsc po pobraniu skóry do przeszczepu. 66045124 ALLEVYN THIN: Opatrunek ALLEVYN THIN jest, przeznaczony do leczenia, odleżyn i owrzodzeń żył, kończyn dolnych o lekkim, wysięku, gojących się wtórnie.
Portuguese	Português	PT	Os pensos ALLEVYN THIN são indicados para: O tratamento de feridas; superficiais com exsudado; ligeiro, incluindo queimaduras; ligeiras e abrasões; Úlceras por pressão; Lesões de perna; Feridas cirúrgicas; Locais dadores de enxertos de pele. 66045124 ALLEVYN THIN: Os pensos ALLEVYN THIN são indicados para o tratamento de úlceras por pressão e úlceras venosas da perna que cicatrizem por segunda intenção com exsudado ligeiro.
Slovak	Slovenčina	SK	Krytia ALLEVYN THIN sú indikované na: Liečbu povrchových rán s miernym exsudátom vrátane menších popálenín a abrázií; Preležaniny; Vredy predkolenia; Pooperačné rany; Miesta kožných štepov. 66045124 ALLEVYN THIN: Krytia ALLEVYN THIN sú indikované na liečbu preležanín a venózných vredov na nohe, ktoré sa hoja sekundárnou intenciou s miernym exsudátom.
Slovenian	Slovenščina	SL	Obloge ALLEVYN THIN so indicirane za: Zdravljenje površinskih ran z blagim izcedkom, vključno z lažjimi opeklinami in odrgninami; Preležanine; Razjede spodnjih okončin; Kirurške rane; Darovalska mesta za kožne presadke. 66045124 ALLEVYN THIN: Obloge ALLEVYN THIN so indicirane za zdravljenje preležanin in venskih razjed spodnjih okončin, ki se celijo s sekundarnim celjenjem z blagim izcedkom.
Spanish	Español	ES	Los apósitos ALLEVYN THIN están indicados para: El tratamiento de heridas superficiales con poco exudado, incluidas abrasiones y quemaduras leves; Úlceras por presión; Úlceras en piernas; Heridas quirúrgicas; Zonas donantes de injertos de piel. 66045124 ALLEVYN THIN: Los apósitos ALLEVYN THIN están indicados para el tratamiento de úlceras por presión y úlceras

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

			venosas en piernas que cicatricen por segunda intención, con exudado leve.
Swedish	Svenska	SE	ALLEVYN THIN förband är avsedda för: Vård av ytliga sår med lätt exsudat, inklusive mindre brännskador och abrasioner; Trycksår; Bensår; Kirurgiska sår; Givarställen där hudgraft tagits. 66045124 ALLEVYN THIN: ALLEVYN THIN förband är indicerade för behandling av trycksår och venösa bensår, som läker med sekundär intention med lätt exsudat
Hungarian	Magyar	HU	Az ALLEVYN THIN kötszer a következő esetekben javallott: Enyhén váladékozó, felületi sebek kezelése, beleértve a kisebb égési sérüléseket és horzsolásokat is Nyomási fekélyek; Lábszárfekélyek; Műtéti sebek; Transzplantációs donorterületek. 66045124 ALLEVYN THIN: Az ALLEVYN THIN kötszerek olyan nyomásfekélyek és vénás lábszárfekélyek kezelésére javallottak, amelyek másodlagos sebgyógyulás révén, enyhe váladékozással gyógyulnak.
Estonian	Eesti	EE	Plaastrite ALLEVYN THIN on näidustused on järgmised: Vähese eksudaadiga pindmiste haavade, sh väikeste põletuste ja marrastuste ravi; Survehaavandid; Jalahaavandid; Kirurgilised haavad; Nahasiiriku doonorkohad. 66045124 ALLEVYN THIN: Plaastrid ALLEVYN THIN on näidustatud teisespingsalt paranevate vähese eksudaadiga lamatishaavandite ja venoosete jalahaavandite ravimiseks.

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

Appendices - European Language Term Translations:

Appendix no.	Language (EN)	Language (Local)	Country Code
Appendix 1	Croatian	Hrvatski	HR
Appendix 2	Czech	Český Jazyk	CZ
Appendix 3	Danish	Dansk	DK
Appendix 4	Dutch	Nederlands	NL
Appendix 5	Finnish	Suomi	FI
Appendix 6	French	Français	FR
Appendix 7	German	Deutsch	DE
Appendix 8	Italian	Italiano	IT
Appendix 9	Latvian	Latviešu	LV
Appendix 10	Polish	Polski	PL
Appendix 11	Portuguese	Português	PT
Appendix 12	Slovak	Slovenčina	SK
Appendix 13	Slovenian	Slovenščina	SL
Appendix 14	Spanish	Español	ES
Appendix 15	Swedish	Svenska	SE
Appendix 16	Hungarian	Magyar	HU
Appendix 17	Estonian	Eesti	EE

Certificate Of Completion

Envelope Id: 00B539925C6547C5BEB0EC6670E5A1F5

Status: Completed

Subject: Complete with DocuSign: 1. DOC-WMTF-039V1 - Draft DoC ALLEVYN THIN .doc

Source Envelope:

Document Pages: 7

Signatures: 1

Envelope Originator:

Certificate Pages: 1

Initials: 0

Ana Paula

AutoNav: Enabled

TJ Smith & Nephew Limited

Envelopeld Stamping: Enabled

101 Hessle Road

Time Zone: (UTC) Dublin, Edinburgh, Lisbon, London

Hull, Hull HU3 2BN

AnaPaula.Azevedo@smith-nephew.com

IP Address: 216.222.214.6

Record Tracking

Status: Original

Holder: Ana Paula

Location: DocuSign

14-Dec-2023 | 15:39

AnaPaula.Azevedo@smith-nephew.com

Signer Events**Signature****Timestamp**

Andrew Daglish

Andrew.Daglish@smith-nephew.com

Senior Regulatory Affairs Specialist

Smith & Nephew Medical Limited

Security Level: Email, Account Authentication
(Required), Login with SSO

Sent: 14-Dec-2023 | 15:41

Viewed: 14-Dec-2023 | 16:06

Signed: 14-Dec-2023 | 16:06

Signature Adoption: Uploaded Signature Image

Signature ID:

303C90DE-917A-4F32-AA0A-BF5C275816BC

Using IP Address: 208.127.123.112

With Signing Authentication via DocuSign password

With Signing Reasons (on each tab):

I approve this document

Electronic Record and Signature Disclosure:

Not Offered via DocuSign

In Person Signer Events**Signature****Timestamp****Editor Delivery Events****Status****Timestamp****Agent Delivery Events****Status****Timestamp****Intermediary Delivery Events****Status****Timestamp****Certified Delivery Events****Status****Timestamp****Carbon Copy Events****Status****Timestamp****Witness Events****Signature****Timestamp****Notary Events****Signature****Timestamp****Envelope Summary Events****Status****Timestamps**

Envelope Sent

Hashed/Encrypted

14-Dec-2023 | 15:41

Certified Delivered

Security Checked

14-Dec-2023 | 16:06

Signing Complete

Security Checked

14-Dec-2023 | 16:06

Completed

Security Checked

14-Dec-2023 | 16:06

Payment Events**Status****Timestamps**