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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 Ltd ².

Manufacturer's Name³	Smith & Nephew Medical Ltd
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:	OPSITE Flexifix OPSITE Flexifix Gentle
Intended Use⁹	<p><u>OPSITE Flexifix</u></p> <ul style="list-style-type: none"> • To retain primary dressings. • To protect skin around stoma and under leg bags. • OPSITE Flexifix is indicated to retain primary wound dressings, e.g., MELOLIN or ALLEVYN Non-Adhesive, or protect the skin from friction. <p><u>OPSITE Flexifix Gentle</u></p> <ul style="list-style-type: none"> • Retain primary wound dressings. • Aid fixation of tubing. • Protect skin from friction and external contamination. • Protect the skin around stoma and under leg bags.
Conformity Assessment Procedure (Annex)¹⁰	N/A
Notified Body Name¹¹	N/A
Notified Body Number¹²	N/A
Verification Certificate(s)¹³	N/A

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Signed on behalf of Smith & Nephew Medical Ltd ¹⁴	
Signature¹⁵	<p>DocuSigned by:</p> <p><i>Amrita Butler</i></p> <p>Signer Name: Amrita Butler Signing Reason: I approve this document Signing Time: 22-Nov-2022 11:41:08 GMT C4EE3BFE6D3C4D78A1A614BF7DD28AA1</p>
Name¹⁶	<u>Amrita Butler</u>
Position¹⁷	<u>Senior Regulatory Affairs Manager</u>
Date¹⁸	22-Nov-2022 11:41:11 GMT
Location¹⁹	<u>Hull, UK</u>
Declaration of Conformity Reference²⁰	DOC-WMTF-002/V8

Product Schedule ²¹			
Product Code / Catalogue Number ²²	Product Description or Product Variant ²³	Risk Classification ²⁴	Basic UDI ²⁵
66000375	OPSITE Flexifix 15cm x 10m	I	5000223SN000092RK
66390375	OPSITE Flexifix 15cm x 10m	I	5000223SN000092RK
5445375	OPSITE Flexifix 15cm x 1m	I	5000223SN000092RK
66390041	OPSITE Flexifix 10cm x 10m	I	5000223SN000092RK
66000041	OPSITE Flexifix 10cm x 10m	I	5000223SN000092RK
66000569	OPSITE Flexifix 5cm x 1m	I	5000223SN000092RK
66000570	OPSITE Flexifix 10cm x 1m	I	5000223SN000092RK
66030569	OPSITE Flexifix 5cm x 1m	I	5000223SN000092RK
66030570	OPSITE Flexifix 10cm x 1m	I	5000223SN000092RK
66320569	OPSITE Flexifix 5cm x 1m	I	5000223SN000092RK
66320570	OPSITE Flexifix 10cm x 1m	I	5000223SN000092RK
66000040	OPSITE Flexifix 5cm x 10m	I	5000223SN000092RK
66390040	OPSITE Flexifix 5cm x 10m	I	5000223SN000092RK
66801195	OPSITE Flexifix Gentle 2.5cm x 5m	I	5000223SN000092RK
66801196	OPSITE Flexifix Gentle 5cm x 5m	I	5000223SN000092RK
66801197	OPSITE Flexifix Gentle 10cm x 5m	I	5000223SN000092RK
36361379	OPSITE Flexifix Gentle 5cm x 1m	I	5000223SN000092RK
36361380	OPSITE Flexifix Gentle 10cm x 1m	I	5000223SN000092RK

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Standards / Common Specification(s) ²⁶ :	
EN ISO 13485:2016/A11:2021	EN ISO 10993-10:2013
EN ISO 14971:2019	EN ISO 10993-18:2009
EN 62366-1:2015	EN ISO 14644-1:2015
EN ISO 15223-1:2021	EN 13726-2:2002
EN ISO 780:2015	EN 13726-3:2003
EN ISO 10993-1:2018	EN ISO 20417:2021
EN ISO 10993-5:2009	

Intended Use European Language Translations ²⁷ :				
Language ²⁸		Code	Intended Use	
EN	Local			
			OPSITE Flexifix	OPSITE Flexifix Gentle
Bulgarian	български език	BG	<p>За задържане на първични превръзки.</p> <p>За защита на кожата около стомата и под торбичките за крака.</p> <p>OPSITE Flexifix е показана за задържане на първичните превръзки на раната, напр. MELOLIN или ALLEVYN Non-Adhesive, или за защита на кожата от триене.</p>	<p>OPSITE Flexifix Gentle е предназначена да задържа първичните раневи превръзки, както и да помага за фиксирането на тръбички.</p> <p>Използва се да предпазва кожата около стома и под преносими уринаторни торбички и може също да предпазва кожата от триене и външно замърсяване.</p>
Croatian	Hrvatski	HR	<p>Služi za pričvršćivanje primarnih obloga.</p> <p>Štiti kožu oko stome i ispod nožnih vrećica za urin.</p> <p>OPSITE Flexifix indiciran je za pričvršćivanje primarnih obloga, npr. neljepljivih obloga MELOLIN ili ALLEVYN Non-Adhesive, ili kao zaštita kože od trenja.</p>	<p>Proizvod OPSITE Flexifix Gentle indiciran je za pričvršćivanje primarnih obloga rane, kao i za učvršćivanje cijevi.</p> <p>Koristi se za zaštitu kože oko stome i ispod nožnih vrećica, a može se koristiti i za zaštitu kože od trenja i vanjske kontaminacije.</p>
Czech	Český Jazyk	CZ	<p>Pro retenci primárního krytí.</p> <p>Pro ochranu kůže kolem stomie a pod sběrnými sáčky na dolní končetinu.</p> <p>OPSITE Flexifix je indikován k retenci</p>	<p>Fólie OPSITE Flexifix Gentle je určena pro fixaci primárního obvazového materiálu na ráně a také jako doplňující fixace hadiček.</p> <p>Používá se k ochraně pokožky kolem stomie a pod sběrné sáčky na dolní</p>

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			primárního krytí ran, např. MELOLIN nebo ALLEVYN Non-Adhesive, nebo k ochraně kůže před třením.	končetinu, přičemž může také chránit kůži před odřeninami a vnějším poraněním.
Danish	Dansk	DK	Til fastholdelse af primære bandager. Til beskyttelse af huden omkring stomier og under benposer.	OPSITE Flexifix Gentle er indikeret til fastholdelse af primære sårbandager så vel som hjælp til fiksering af slanger. Det bruges til at beskytte huden omkring stomier og under benposer, og kan også beskytte huden mod friktion og ekstern kontaminering.
Dutch	Nederlands	NL	Vasthouden van primaire verband. Bescherming van de huid rond stoma's en onder beenzakken. OPSITE Flexifix er indiceret til fastholdelse af primære sårbandager, f.eks. MELOLIN eller ALLEVYN Non-Adhesive, eller til beskyttelse af huden mod friktion.	OPSITE Flexifix Gentle is bedoeld voor fixatie van primair wondverband en als hulpmiddel om slangen te fixeren. Het wordt gebruikt om de huid te beschermen rondom stoma's en onder beenzakken, en om de huid te beschermen tegen wrijving en besmetting van buitenaf.
Estonian	Eesti	EE	Primaarsete sidemete kinnitamiseks. Stoomat ümbritseva ja jalakoti aluse naha kaitseks. OPSITE Flexifix on näidustatud primaarsete haavasidemete (nt MELOLIN või ALLEVYN Non-Adhesive) kinnitamiseks ning naha kaitseks hõõrdumise eest.	OPSITE Flexifix Gentle on mõeldud primaarse haavasideme kinnitamiseks, aga ka abivahendiks vooliku kinnitamisel. Kasutatakse stoomat ümbritseva ja jalakotti aluse naha kaitsmiseks ning see võib nahka kaitsta ka hõõrdumise ja välise mustuse eest.
Finnish	Suomi	FI	Primaarisidosten paikallaan pitäminen. Ihon suojaaminen avanteen ympärillä ja jalkapussien alla. OPSITE Flexifix on tarkoitettu primaaristen haavasidosten, kuten MELOLIN- tai ALLEVYN Non-Adhesive	OPSITE Flexifix Gentle on tarkoitettu pitämään ensisijaisia haavasidoksia paikallaan sekä avuksi letkun kiinnittämisessä. Sitä käytetään ihon suojaamiseen avanteen ympärillä ja jalkapussien alla. Se voi myös suojata ihoa hankaukselta ja ulkoiselta kontaminoitumiselta.

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			sidosten, paikallaan pitämiseen tai ihon suojaamiseen hankaukselta.	
French	Français	FR	<p>Fixation des pansements primaires.</p> <p>Protection de la peau autour des stomies et sous les sacs de jambe.</p> <p>OPSITE Flexifix est indiqué pour la fixation de pansements primaires tels que MELOLIN ou ALLEVYN Non-Adhesive, ou pour la protection de la peau contre les frottements.</p>	<p>OPSITE Flexifix Gentle est indiqué pour la fixation de pansements primaires et pour faciliter la fixation d'une tubulure.</p> <p>Il est utilisé pour protéger la peau autour des stomies et sous les poches de jambe. Il permet également de protéger la peau contre la friction et la contamination externe.</p>
German	Deutsch	DE	<p>Zur sicheren Fixierung von primären Wundauflagen.</p> <p>Zum Schutz der Haut um das Stoma und unter den Beinbeuteln.</p> <p>OPSITE Flexifix ist für eine sichere Fixierung von primären Wundauflagen, wie z. B. MELOLIN oder ALLEVYN Non-Adhesive, oder zum Schutz der Haut vor Reibung bestimmt.</p>	<p>OPSITE Flexifix Gentle ist für die sichere Fixierung von primären Wundauflagen sowie als Hilfe bei der Fixierung von Schläuchen indiziert.</p> <p>Es wird zum Schutz der Haut um das Stoma und unter den Beinbeuteln verwendet und kann zudem die Haut vor Reibung und externer Kontamination schützen.</p>
Greek	Ελληνικά	GR	<p>Να συγκρατεί κύρια επιθέματα.</p> <p>Να προστατεύει το δέρμα γύρω από τη στομία και κάτω από τους ουροσυλλέκτες περιπάτου.</p> <p>Το OPSITE Flexifix ενδείκνυται για τη συγκράτηση κύριων επιθεμάτων τραυμάτων, π.χ. MELOLIN ή ALLEVYN Non-Adhesive, ή για την προστασία του δέρματος από την τριβή.</p>	<p>Το OPSITE Flexifix Gentle ενδείκνυται για τη συγκράτηση κύριων επιθεμάτων τραυμάτων καθώς και για την υποβοήθηση της στερέωσης της σωλήνωσης.</p> <p>Χρησιμοποιείται για την προστασία του δέρματος γύρω από τη στομία και κάτω από τους ουροσυλλέκτες περιπάτου και μπορεί επίσης να προστατεύει το δέρμα από την τριβή και τους εξωτερικούς μολυσματικούς παράγοντες.</p>
Hungarian	Magyar	HU	<p>Az elsődleges kötések megtartása.</p> <p>A bőr védelme a sztóma körül és a lábon elhelyezett vizeletgyűjtő zsákok alatt.</p> <p>Az OPSITE Flexifix az elsődleges sebkötések – pl. a MELOLIN vagy</p>	<p>Az OPSITE Flexifix Gentle elsődleges sebfedők, valamint csövek rögzítésére használható.</p> <p>Megvédi a bőrt a sztóma körül és a vizeletgyűjtő lábszák alatt, valamint óvja a bőrt a súrlódástól és a külső szennyeződéstől.</p>

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			<p>ALLEVYN Non-Adhesive kötése – megtartására, illetve a bőr súrlódással szembeni védelmére javallott.</p>	
Italian	Italiano	IT	<p>Per il fissaggio delle medicazioni principali.</p> <p>Per la protezione della cute intorno allo stoma e sotto le sacche da gamba.</p> <p>OPSITE Flexifix è indicato per il fissaggio delle medicazioni primarie, ad es. MELOLIN o ALLEVYN Non-Adhesive oppure per proteggere la cute dall'attrito.</p>	<p>L'OPSITE Flexifix Gentle è indicata per fissare le medicazioni primarie delle ferite ma anche per il fissaggio di tubi.</p> <p>Viene utilizzata per proteggere la cute intorno allo stoma e sotto le sacche da gamba e può anche proteggere la cute da frizioni e contaminazioni esterne.</p>
Latvian	Latviešu	LV	<p>Saglabāt sākotnējos pārsējus.</p> <p>Aizsargāt ādu ap atveri un zem urīna savācējmaisiem.</p> <p>OPSITE Flexifix ir indicēts sākotnējo brūces pārsēju saglabāšanai, t.i., MELOLIN vai ALLEVYN Non- Adhesive, vai ādas aizsargāšanai no berzes.</p>	<p>OPSITE Flexifix Gentle ir indicēts sākotnējo brūces pārsēju saglabāšanai, kā arī cauruļu nostiprināšanai. To izmanto, lai aizsargātu ādu ap atveri un zem urīna savācējmaisiem, un tas var aizsargāt ādu arī no berzes un ārēja piesārņojuma.</p>
Lithuanian	Lietuvių	LT	<p>Išsaugoti pirminius tvarsčius.</p> <p>Apsaugoti odą aplink stomą ir po urostominiais kojų maišeliais.</p> <p>OPSITE Flexifix“ indikuojamas išsaugoti pirminius žaizdos tvarsčius, pavyzdžiui, MELOLIN ar „ALLEVYN Non-Adhesive“ arba apsaugoti odą nuo trinties.</p>	<p>OPSITE Flexifix Gentle skirta prilaikyti pagrindinius žaizdų tvarsčius ir padėti pritvirtinti vamzdelius.</p> <p>Ji naudojama odai aplink stomą ir po urostominiais kojų maišeliais apsaugoti, taip pat gali apsaugoti odą nuo trinties ir išorinio užteršimo.</p>
Polish	Polski	PL	<p>Aby zachować pierwotne opatrunki.</p> <p>Aby chronić skórę wokół stomii i pod workami do zbiórki moczu.</p> <p>Produkt OPSITE Flexifix jest wskazany do stosowania w celu zachowania pierwotnego opatrunku rany, np. produktów MELOLIN lub</p>	<p>Przylepiec OPSITE Flexifix Gentle jest przeznaczony do mocowania pierwotnych opatrunków ran oraz drenów.</p> <p>Chroni skórę wokół stomii i pod workami do zbiórki moczu. Dodatkowo pomaga chronić skórę przed otarciami i skażeniami zewnętrznymi.</p>

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			ALLEVYN Non-Adhesive, lub ochrony skóry	
Portuguese	Português	PT	<p>Para reter pensos primários.</p> <p>Para proteger a pele em volta do estoma e sob os sacos para perna.</p> <p>OPSITE Flexifix é indicado para reter pensos primários, p.ex.: MELOLIN ou ALLEVYN Non-Adhesive, ou para proteger a pele de fricção.</p>	<p>O OPSITE Flexifix Gentle é indicado para reter os pensos primários de feridas, assim como auxiliar na fixação da tubagem.</p> <p>É utilizado para proteger a pele em volta do estoma e sob os sacos para perna e também pode proteger a pele de fricção e da contaminação externa.</p>
Romanian	Română	RO	<p>Pentru a fixa pansamentele principale.</p> <p>Pentru a proteja pielea din jurul stomei și de sub pungile pentru picior.</p> <p>OPSITE Flexifix este indicat pentru fixarea pansamentelor principale, de ex. MELOLIN sau ALLEVYN Non-Adhesive, sau pentru protejarea pielii împotriva frecării.</p>	<p>OPSITE Flexifix Gentle este indicat pentru reținerea pansamentelor primare pentru plăgi, precum și ca ajutor pentru fixarea tuburilor.</p> <p>Este folosit pentru protejarea pielii în jurul stomelor și a pungilor de picior și, de asemenea, poate proteja pielea împotriva fricțiunii și contaminării externe.</p>
Slovak	Slovenčina	SK	<p>Na zachovanie primárnych obvazov.</p> <p>Na ochranu kože okolo stómie a pod nožnými vreckami na moč.</p> <p>OPSITE Flexifix je indikovaný na zachovanie primárnych obvazov na rane, napr. MELOLIN alebo ALLEVYN Non-Adhesive, alebo na ochranu kože pred trením.</p>	<p>OPSITE Flexifix Gentle je indikované na pridržavanie primárnych obvazov na rany a na uľahčenie fixácie hadičiek.</p> <p>Používa sa na ochranu pokožky okolo stómy a vreciek s upevnením na nohe. Taktiež môže pokožku chrániť pred trením a externým znečistením.</p>
Slovenian	Slovenščina	SI	<p>Za zadržanje primarnih oblog.</p> <p>Za zaščito kože okoli stome in pod nožnimi vrečkami.</p> <p>Sujeción de los apósitos primarios.</p> <p>OPSITE Flexifix je indiciran za zadržanje primarnih oblog za rane, npr. MELOLIN ali ALLEVYN Non-</p>	<p>OPSITE Flexifix Gentle je indiciran za zadržanje primarnih oblog za rane in za pomoč pri fiksaciji cevja.</p> <p>Uporablja se za zaščito kože okoli stome in pod nožnimi vrečkami, kožo pa lahko zaščiti tudi pred trenjem in zunanjo kontaminacijo.</p>

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			Adhesive, ali za zaščito kože pred trenjem.	
Spanish	Español	ES	<p>Sujeción de los apósitos primarios.</p> <p>Protección de la piel alrededor del estoma y debajo de las bolsas para la piernas.</p> <p>OPSITE Flexifix está indicado para sujetar apósitos para heridas primarios, p. ej., MELOLIN o ALLEVYN Non-adhesive, o para proteger la piel de la fricción.</p>	<p>OPSITE Flexifix Gentle está indicado para sujetar apósitos para heridas primarios y ayudar a la fijación del tubo.</p> <p>Se utiliza para proteger la piel alrededor del estoma y debajo de las bolsas de las piernas, y también puede proteger la piel de la fricción y la contaminación externa.</p>
Swedish	Svenska	SE	<p>För att bibehålla primära förband.</p> <p>För att skydda hud runt stomi och under benpåsar.</p> <p>OPSITE Flexifix är indikerad för att bibehålla primära förband, t.ex. MELOLIN eller ALLEVYN Non-Adhesive, eller för att skydda huden mot friktion.</p>	<p>OPSITE Flexifix Gentle indikeras för att fästa primära sårförband och som hjälpmedel för att fixera slangar.</p> <p>Det används för att skydda huden runt stomier och under benpåsar, och kan även skydda huden mot friktion och extern kontamination.</p>

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

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Appendix 17	Romanian	Română	RO
Appendix 18	Slovak	Slovenčina	SK
Appendix 19	Slovenian	Slovenščina	SL
Appendix 20	Spanish	Español	ES
Appendix 21	Swedish	Svenska	SE

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Certificate Of Completion

Envelope Id: 3C13F08C24F44C6CAA4BADF52A3F3EA9	Status: Completed
Subject: Complete with DocuSign: DOC-WMTF-002 V8 OPSITE Flexifix (2).doc	
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Document Pages: 9	Signatures: 1
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Signature	Timestamp
<p>Amrita Butler</p> <p>Amrita.Butler@smith-nephew.com</p> <p>Senior RA Manager</p> <p>Security Level: Email, Account Authentication (Required)</p> <p><i>Amrita Butler</i></p> <p>Signature Adoption: Pre-selected Style</p> <p>Signature ID: C4EE3BFE-6D3C-4D78-A1A6-14BF7DD28AA1</p> <p>Using IP Address: 216.222.214.6</p> <p>With Signing Authentication via DocuSign password</p> <p>With Signing Reasons (on each tab):</p> <p>I approve this document</p>	<p>Sent: 22-Nov-2022 11:21</p> <p>Viewed: 22-Nov-2022 11:40</p> <p>Signed: 22-Nov-2022 11:41</p>

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Editor Delivery Events

Status **Timestamp**

Agent Delivery Events

Status **Timestamp**

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Envelope Summary Events

Status **Timestamps**

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Payment Events

Status **Timestamps**