

Smith & Nephew Medical Limited  
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England

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Smith+Nephew

## EUROPEAN DECLARATION OF CONFORMITY <sup>1</sup>

Declaration confirms that the product listed below meets: Regulation 2017/745 and is issued under the sole responsibility of Smith & Nephew Medical Limited<sup>2</sup>.

<b>Manufacturer's Name<sup>3</sup></b>	Smith & Nephew Medical Limited
<b>Business Address<sup>4</sup></b>	101 Hessle Road, Hull, HU3 2BN, United Kingdom
<b>Single Registration Number (SRN) <sup>5</sup></b>	GB-MF-000017580
<b>European Authorised Representative<sup>6</sup></b>	Smith & Nephew Operations B.V.
<b>Business Address<sup>7</sup></b>	Bloemlaan 2, 2132 NP Hoofddorp, Netherlands
<b>Product Name<sup>8</sup>:</b>	JELONET
<b>Intended Use<sup>9</sup></b>	<p>The range of wounds on which JELONET Dressings may be used include:</p> <ul style="list-style-type: none"> <li>• Burns such as minor burns and scalds</li> <li>• Donor and recipient graft sites</li> <li>• Skin loss wounds</li> <li>• Lacerations</li> <li>• Abrasions</li> <li>• Chronic wounds i.e.: leg ulcers or pressure ulcers</li> </ul> <p>&amp;</p> <p>JELONET Dressings are designed for use on minor burns, scalds and leg ulcers.</p>
<b>Conformity Assessment Procedure (Annex)<sup>10</sup></b>	IX
<b>Notified Body Name<sup>11</sup></b>	BSI Group The Netherlands B. V
<b>Notified Body Number<sup>12</sup></b>	No. 2797
<b>Verification Certificate(s)<sup>13</sup></b>	732832


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<b>Signed on behalf of Smith &amp; Nephew Medical Limited<sup>14</sup></b>	
<b>Signature<sup>15</sup></b>	 <p>DocuSigned by: Sam Greenhalgh Signer Name: Sam Greenhalgh Signing Reason: I approve this document Signing Time: 18-Aug-2023   10:47:46 BST 1C73ED93193D4889F66F071859C80BC</p>
<b>Name<sup>16</sup></b>	Sam Greenhalgh
<b>Position<sup>17</sup></b>	Regulatory Affairs Director
<b>Date<sup>18</sup></b>	18 <sup>th</sup> August 2023
<b>Location<sup>19</sup></b>	Hull
<b>Declaration of Conformity Reference<sup>20</sup></b>	DOC-WMTF-035/V1

<b>Product Schedule<sup>21</sup></b>			
<b>Product Code / Catalogue Number<sup>22</sup></b>	<b>Product Description or Product Variant<sup>23</sup></b>	<b>Risk Classification<sup>24</sup></b>	<b>Basic UDI<sup>25</sup></b>
66000678	JELONET 5cm x 5cm	I Ib	5000223SN000126RB
66007450	JELONET 10cm x 10cm	I Ib	5000223SN000126RB
66320338	JELONET 10cm x10cm	I Ib	5000223SN000126RB
66320572	JELONET 5cm x 5cm	I Ib	5000223SN000126RB
66801534	JELONET 10cm x10cm	I Ib	5000223SN000126RB
7403	JELONET 5cm x5cm	I Ib	5000223SN000126RB
7404	JELONET 10cm x 10cm	I Ib	5000223SN000126RB
7409	JELONET 10cm x10cm	I Ib	5000223SN000126RB
7415	JELONET ON A ROLL (JOAR) 15cm x200cm	I Ib	5000223SN000126RB
7459	JELONET 10cm x 40cm	I Ib	5000223SN000126RB

<b>Standards / Common Specification(s)<sup>26</sup>:</b>
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 10993-23:2021
EN ISO 20417:2021
IEC 62366-1: 2015/AMD 1:2020

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EN ISO 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 Translations<sup>27</sup>:

Language <sup>28</sup>		Code	Intended Use
EN	Local		
Bulgarian	български език	BG	Диапазонът от рани, за които могат да се използват превръзките JELONET, включва: • Изгаряния, например малки изгаряния и попарвания; • Донорски и реципиентни места на присадки; • Рани със загуба на кожа; • Лацерации • Абразии; • Хронични рани, т.е.: рани на краката или декубитални рани
Croatian	Hrvatski	HR	Mezi typy ran, na něž lze obvaz JELONET použít, patří: • popáleniny, jako jsou drobné popáleniny a opařeniny; • dárcovská a příjemcovská místa kožních štěpů; • poranění se ztrátou pokožky; • tržné rány; • odřeny; • chronické rány, např. Bércové; vředy nebo proleženiny.
Czech	Český Jazyk	CZ	Mezi typy ran, na něž lze obvaz JELONET použít, patří: • popáleniny, jako jsou drobné popáleniny a opařeniny; • dárcovská a příjemcovská místa kožních štěpů; • poranění se ztrátou pokožky; • tržné rány; • odřeny; • chronické rány, např. Bércové vředy nebo proleženiny
Danish	Dansk	DK	Typen af sår, hvorpå JELONET-kompresser kan bruges, omfatter: • Forbrændinger såsom mindre forbrændinger eller skoldninger; • Steder, hvor donorhud hentes eller transplanteres; • Sår med hudtab; • Rifter; • Hudafskrabninger; • Kroniske sår, f.eks. bensår eller tryksår
Dutch	Nederlands	NL	Soorten wonden waarvoor JELONET kompressen gebruiktkunnen worden: • Brandwonden, zoals kleine brandwonden en brandblaren; • Donor- en receptorplaatsen bij huidtransplantatie; • Open wonden; • Snijwonden; • Schaafwonden; • Chronische wonden, zoals beenulcera of decubituswonden
Estonian	Eesti	EE	JELONET sidemeid võib kasutada järgmiste haavadega: • põletused, nagu pindmised põletused ja väiksemad; põletushaavad; • doonori ja retsiipiendi siirdamiskohad; • nahakaotusega haavad; • rebendid; • marrastused; • kroonilised haavad, st: jalahaavandid või survehaavandid
Finnish	Suomi	FI	Haavatyyppeihin, joihin JELONET-sidoksia voidaan käyttää, sisältyvät: • palovammat, kuten lievät palovammat ja polttohaavat; • ihosiirännäisten otto- ja asetuspaiikat; • ihonmenetyshaavat; • repalehaavat; • hiertymät; • krooniset haavat eli: säarihaavat tai painehaavat
French	Français	FR	Les pansements JELONET peuvent être utilisés sur les plaies suivantes: • Brûlures telles que des brûlures légères et des brûlures causées par un

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			<p>liquide bouillant; • Sites donneurs et receveurs de greffe; • Plaies avec perte cutanée; • Lacérations; • Abrasions; • Plaies chroniques, c.-à-d.: ulcères de jambe ou escarres dues à la pression &amp;</p> <p>Les pansements JELONET sont conçus pour une utilisation sur les brûlures légères, les brûlures causées par un liquide bouillant et les ulcères de jambe.</p>
German	Deutsch	DE	<p>Die Wunden, bei denen JELONET-Verbände angewendet werden können, sind u. a.:</p> <ul style="list-style-type: none"> <li>• Verbrennungen wie leichten Verbrennungen und Verbrühungen;</li> <li>• Transplantationsstellen bei Spendern und Empfängern;</li> <li>• Wunden mit Hautverlust;</li> <li>• Risswunden;</li> <li>• Schürfwunden;</li> <li>• Chronische Wunden, wie z. B.; Beingeschwüre oder Druckgeschwüre</li> </ul>
Greek	Ελληνικά	GR	<p>Το φάσμα των τραυμάτων στα οποία μπορούν να χρησιμοποιηθούν οι βαζελινούχες γάζες JELONET περιλαμβάνει: • Εγκαύματα, όπως μικροεγκαύματα και ζεματίσματα; • Περιοχές μοσχεύματος δότη και λήπτη; • Τραύματα απώλειας δέρματος; • Εκδορές; • Αμυχές; • Χρόνιες πληγές π.χ.: έλκη στα πόδια ή έλκη εκ πίεσης</p>
Hungarian	Magyar	HU	<p>A JELONET kötszerek a következő sebekre használhatók: • Égési sérülések, például kisebb égési sérülések és forrázások; • Graft donor és befogadó helyek; • Bőrvesztéses sebek; • Vágások • Horzsolások; • Krónikus sebek, pl.: lábszárfekélyek vagy nyomási fekélyek</p>
Italian	Italiano	IT	<p>La gamma di ferite su cui è possibile utilizzare JELONET comprende: • Ustioni come ustioni superficiali e scottature; • Siti di innesto e prelievo Cutaneo; • Ferite con perdita di sostanza; • Lacerazioni; • Abrasioni; • Ferite croniche (ad es., ulcere degli arti inferiori e ulcere da pressione).</p>
Latvian	Latviešu	LV	<p>Brūču klāsts, uz kurām var izmantot JELONET pārsējus, ietver: • apdegumus, piem., nelielus apdegumus un applaucējumus; • donoru un saņēmēju transplantācijas vietas; • ādas zuduma brūces; • plēstas brūces; • nobrāzumus; • hroniskas brūces, t.i.: kāju čūlas vai izgulējumus.</p>
Lithuanian	Lietuvių	LT	<p>„JELONET“ tvarščius galima naudoti šioms žaizdoms: • nudegimams, pavyzdžiui, nesunkiems nudegimams ar nuplikymams; • donorinėms ir recipientinėms transplantavimo vietoms; • žaizdoms, kai netekta odos; • plėstinėms žaizdoms; • nubrozdinimams; • lėtinėms žaizdoms, t. y., kojų opoms ar spaudimo opoms.</p>
Polish	Polski	PL	<p>Do ran, w przypadku których można stosować opatrunki JELONET należą: • Oparzenia, takie jak drobne; oparzenia i oparzenia; • Miejsca</p>

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			przeszczepów dawcy ibiorcy; • Rany z utratą skóry • Rany cięte; • Otarcia; • Rany przewlekłe, np. owrzodzenia kończyn dolnych lub odleżyny
Portuguese	Português	PT	As feridas onde os pensos JELONET podem ser usados incluem: • Queimaduras tais como pequenas queimaduras e queimadelas; • Locais dadores e recetores de enxertos; • Feridas com perda de pele; • Lacerações; • Abrasões; • Feridas crónicas, p. ex. Lesões nas pernas ou úlceras de pressão
Romanian	Română	RO	Seria de plăgi pe care pot fi utilizate pansamentele JELONET cuprinde: • Arsuri precum arsuri minore și Opăririi; • Sitisuri de grefă donator șiI primitor; • Plăgi cu pierdere a pielii; • Lacerații; • Abraziuni; • Plăgi cronice, adică: ulcere ale picioarelor sau escare de decubit
Slovak	Slovenčina	SK	Typy rán, pri ktorých môžu byť krytia JELONET použité, sú: • Popáleniny, ako napr. Menšie popáleniny a obarenia; • Plochy použité na štepy darcu a príjemcu; • Rany so stratou kože; • Tržné rany; • Odreniny; • Chronické rany, t. j. : vredy predkola alebo preležaniny
Slovenian	Slovenščina	SI	Rane, ki so primerne za uporabo oblog JELONET, so naslednje: • Opeklina, kot so manjše; opeklina in odrgnine • Darovalska in sprejemna mesta presadkov; • Rane zaradi izgube kože; • Raztrganine; • Odrgnine; • Kronične rane tj.: razjede spodnjih okončin, razjede zaradi pritiska
Spanish	Español	ES	La variedad de heridas en las que pueden utilizarse los vendajes JELONET incluyen: • Quemaduras como quemaduras leves y escaldaduras; • Sitios de injertos de donante y receptor; • Heridas con pérdida de piel; • Laceraciones; • Abrasiones; • Heridas crónicas, esto es: úlceras en piernas o úlceras por presión
Swedish	Svenska	SE	Utbudet av sår, som JELONET-förband kan användas på, inkluderar: • Brännskador såsom mindre brännskador och skållningar; • Givar- och Mottagartransplantationsställen; • Sår med hudförlust; • Rivsår; • Skrubbsår; • Kroniska sår, dvs: bensår eller trycksår
Norwegian	Norsk	NO	Sårtyper som JELONET-kompresser kan brukes på, inkluderer: • Brannsåre som mindre brannsåre og skåldeskader; • Transplantatsteder hos donor; og mottaker; • Sår med hudtap; • Laserasjoner; • Skrubbsår; • Kroniske sår, dvs. bensår eller trykksår
Turkish	Türkçe	TR	JELONET Sargılarının üzerinde kullanılabileceği yara türlerine şunlar dahildir: • Küçük yanıklar ve haşlanma gibi yanıklar; • Donör ve alıcı greft bölgeleri; • Cilt kaybı olan yaralar; • Laserasyonlar • Abrazyonlar; • Kronik yaralar, yani bacak ülserleri

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			veya bası ülserleri & JELONET Sargılar, küçük yanıklar, haşlanmalar ve bacak ülserlerinde kullanım için tasarlanmıştır.
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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

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