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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 Ltd.[2]

Manufacturer's Name[3]	Smith & Nephew Medical Ltd.
Business Address[4]	101 Hessle Road, Hull, HU3 2BN, United Kingdom
Single Registration Number (SRN) [5]	GB-MF-000017580
European Authorised Representative[6]	Smith & Nephew Operations B.V.
Business Address[7]	Bloemlaan 2, 2132 NP Hoofddorp, Netherlands
Product Name: *(see attached schedule for product codes/catalogue numbers)[8]*	MELOLIN/CUTILIN/MELOLITE
Intended Use[9] *See table for other languages*	MELOLIN Dressing Pads are designed for use on cuts, grazes, minor burns and stitches.
Conformity Assessment Procedure (Annex)[10]	Annex XI
Notified Body Name[11]	BSI Group The Netherlands B.V
Notified Body Number[12]	2797
Verification Certificate(s)[13]	MDR 737173

Signed on behalf of Smith & Nephew Medical Ltd.[14]	
Signature[15]	DocuSigned by: Sam Greenhalgh Signer Name: Sam Greenhalgh Signing Reason: I approve this document Signing Time: 17-Mar-2022 | 08:35:14 PDT 1C73ED93193D48889F66F071859C80BC
Name[16]	Sam Greenhalgh
Position[17]	Senior Regulatory Affairs Manager
Date[18]	17-Mar-2022 | 08:35:34 PDT
Location[19]	Hull, UK
Declaration of Conformity Reference[20]	DOC-WMTF-001/V1

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Product Schedule[21]			
Product Code / Catalogue Number[22]	**Product Description or Product Variant[23]**	**Risk Classification[24]**	**Basic UDI[25]**
4811	MELOLITE 5x7.5cm Carton of 100	Class IS	5000223SN000091RH
4812	MELOLITE 10x7.5cm Carton of 100	Class IS	5000223SN000091RH
4814	MELOLITE 2x7.5cm Carton of 100	Class IS	5000223SN000091RH
66964941	MELOLIN Sterile 10x10cm Carton of 100	Class IS	5000223SN000091RH
66964940	MELOLIN Sterile 5x5cm Carton of 100	Class IS	5000223SN000091RH
66964939	MELOLIN Sterile 20x10cm Carton of 100	Class IS	5000223SN000091RH
66974932	MELOLIN Sterile 5x5cm Carton of 25	Class IS	5000223SN000091RH
66974933	MELOLIN Sterile 10x10cm Carton of 10	Class IS	5000223SN000091RH
66974939	MELOLIN Sterile 20x10cm Carton of 100	Class IS	5000223SN000091RH
66974940	MELOLIN Sterile 5x5cm Carton of 100	Class IS	5000223SN000091RH
66974941	MELOLIN Sterile 10x10cm Carton of 100	Class IS	5000223SN000091RH
36361357	MELOLIN Sterile 5x5cm Carton of 5	Class IS	5000223SN000091RH
36361358	MELOLIN Sterile 10x10cm Carton of 3	Class IS	5000223SN000091RH
36101013	MELOLIN Sterile 5x5cm Carton of 100	Class IS	5000223SN000091RH
36101113	MELOLIN Sterile 10x10cm Carton of 100	Class IS	5000223SN000091RH
36101213	MELOLIN Sterile 10x20cm Carton of 100	Class IS	5000223SN000091RH
66801536	MELOLIN Sterile 10x10cm Carton of 3	Class IS	5000223SN000091RH
66000381	MELOLIN Sterile (Consumer Select) 5x5cm Case of 3000	Class IS	5000223SN000091RH
66000382	MELOLIN Sterile (Consumer Select) 10x10cm Case of 800	Class IS	5000223SN000091RH
66000603	MELOLIN Sterile (Consumer Select) 10x10cm Carton of 5	Class IS	5000223SN000091RH
66000653	MELOLIN ADHESIVE (Consumer Select) 6x8.3cm Carton of 6	Class IS	5000223SN000091RH
66000654	MELOLIN ADHESIVE (Consumer Select) 10x8cm Carton of 6	Class IS	5000223SN000091RH
66030260	MELOLIN Sterile (Consumer Select) 5x5cm Carton of 25	Class IS	5000223SN000091RH
66800707	MELOLIN Sterile (Consumer Select) 10x20cm Carton of 5	Class IS	5000223SN000091RH
66965755	MELOLIN Sterile (Consumer Select) 5x5cm Carton of 100	Class IS	5000223SN000091RH

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66965756	MELOLIN Sterile (Consumer Select) 10x10cm Carton of 100	Class IS	5000223SN000091RH
66030261	MELOLIN Sterile (Consumer Select) 10x10cm Carton of 10	Class IS	5000223SN000091RH
66965757	MELOLIN Sterile (Consumer Select) 20x10cm Carton of 100	Class IS	5000223SN000091RH
66000602	MELOLIN Sterile (Consumer Select) 5x5cm Carton of 5	Class IS	5000223SN000091RH
66240261	MELOLIN Sterile (Consumer Select) 10x10cm Carton of 5	Class IS	5000223SN000091RH
66240602	MELOLIN Sterile (Consumer Select) 5x5cm Carton of 5	Class IS	5000223SN000091RH
76240	CUTILIN Sterile 5x5cm Carton of 100	Class IS	5000223SN000091RH
76242	CUTILIN Sterile 10x10cm Carton of 100	Class IS	5000223SN000091RH
76243	CUTILIN Sterile 10x20cm Carton of 100	Class IS	5000223SN000091RH
36361374	CUTILIN Sterile 5x5cm Carton of 5	Class IS	5000223SN000091RH
36361375	CUTILIN Sterile 10x10cm Carton of 5	Class IS	5000223SN000091RH

Standards / Common Specification(s)[26]:	
Standard/Common Specification Number[27]	**Title**
EN ISO 780: 2015	Packaging – Distribution Packaging- Graphical Symbols for Handling and Storage of Packages
EN ISO 13485: 2016	Medical Devices – Quality Management Systems- Requirements for Regulatory Purposes
EN ISO 15223-1: 2016	Medical Devices – Symbols to be used with Medical Devices Labels, Labelling and Information to be Supplied – Part 1: General Requirements
EN ISO 14971:2012	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 10993-1:2018	Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process
EN 1041: 2008+A1:2013	Information Supplied by the Manufacturer
EN 13726-2:2002	Test methods for primary wound dressings – part 2 – Moisture Vapour Transmission
EN 62366-1: 2015	Medical devices. Application of usability engineering to medical devices
EN ISO 10993-3:2014	Biological evaluation of medical devices — Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
EN ISO 10993-5:2009	Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-10	Biological evaluation of medical devices — Part 10: Tests for skin sensitisation
EN ISO 10993-17	Biological evaluation of medical devices — Part 17: Toxicological risk assessment of medical device constituents
EN ISO 10993-7:2008	Biological evaluation of medical devices. Ethylene oxide sterilization residuals
EN ISO 10993-18:2009	Biological evaluation of medical devices. Chemical characterization of materials
EN ISO 11135:2014	Sterilisation of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices

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EN ISO 17665-1:2006	Sterilisation of health care products — Moist heat— Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
ISO 11607-1:2019	Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems
ISO 11607-2:2019	Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes
EN 556-1:2001/AC:2006	Sterilisation of medical devices. Requirements for medical devices to be designated "STERILE". Requirements for terminally sterilized medical devices
EN ISO 14644-1:2015	Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness by particle concentration

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Intended Use European Language Translations[28]:

Language[29]	Code	Intended Use
Danish	DK	MELOLIN kompresser er designet til snitsår, hudafskrabninger, mindre forbrændinger samt cicatricer.
Dutch	NL	MELOLIN Dressing Pads zijn geschikt voor gebruik bij snijwonden, schaafwonden, lichte brandwonden en hechtingen.
Finnish	FI	MELOLIN-haavatyynyt on suunniteltu käytettäväksi naarmujen, viiltohaavojen ja pienempien palovammojen hoidossa.
French	FR	Les compresses absorbantes MELOLIN sont conçues pour couvrir les coupures, les égratignures, les brûlures mineures et les sutures.
German	DE	MELOLIN-Wundauflagen sind für Schnitt- und Schürfwunden, leichte Verbrennungen und genähte Wunden bestimmt.
Norwegian	NO	MELOLIN bandasjeputer er designet for bruk på kutt, skrubbsår, mindre brannsår og sting.
Swedish	SE	MELOLIN kompress används vid skärsår, skrubbsår, mindre brännsår och suturerade sår.

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Language[29]	Code	No.	Translated Terms
Bulgarian:	**BG**	1	ЕВРОПЕЙСКА ДЕКЛАРАЦИЯ ЗА СЪОТВЕТСТВИЕ
		2	Декларацията потвърждава, че посоченият по-долу продукт съответства на: Регламент 2017/745, [въведете друго уместно европейско законодателство, според приложимото] и се издава единствено на отговорност на име на законния производител
		3	Име на производител
		4	Бизнес адрес
		5	Единен регистрационен номер (ЕРН)
		6	Упълномощен представител за Европа
		7	Бизнес адрес
		8	Име на продукт: (вижте приложения опис за продуктови кодове/каталожни номера)
		9	Предназначение: Вижте таблицата за други езици
		10	Процедура за оценяване на съответствието (Приложение)
		11	Име на нотифициран орган
		12	Номер на нотифициран орган
		13	Сертификат(и) за проверка
		14	Подписан от името на име на законния производител
		15	Подпис
		16	Име
		17	Длъжност
		18	Дата
		19	Местоположение
		20	Справка за декларация за съответствие
		21	Продуктов опис
		22	Продуктов код / Каталожен номер
		23	Описание на продукта или Вариант на продукта
		24	Класификация в зависимост от риска
		25	Основен уникален идентификатор на изделията - идентификатор на изделията
		26	Стандарти / Обща(и) спецификация(и)
		27	Стандарт/Номер на обща спецификация

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		28	Предназначение: Преводи на европейски езици
		29	Език

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Language[29]	Code	No.	Translated Terms
Croatian:	**HR**	1	EUROPSKA IZJAVA O SUKLADNOSTI
		2	Izjavom se potvrđuje da je niže navedeni proizvod u skladu s: Uredbama 2017/745, [unesite ostale mjerodavne Europske zakone, kako je primjenjivo]. Odgovornost za njeno izdavanje snosi isključivo [naziv proizvođača]
		3	Naziv proizvođača
		4	Adresa poslovanja
		5	Jedinstveni registracijski broj (SRN)
		6	Ovlašteni zastupnik za Europu
		7	Adresa poslovanja
		8	Naziv proizvoda: (šifre proizvoda/kataloške brojeve potražite u priloženom dodatku)
		9	Namjena: Proučite tablicu za ostale jezike
		10	Postupak ocjenjivanja sukladnosti (Prilog)
		11	Naziv prijavljenog tijela
		12	Broj prijavljenog tijela
		13	Potvrda (potvrde) o provjeri
		14	Potpisao/-la u ime [naziv proizvođača]
		15	Potpis
		16	Ime i prezime
		17	Funkcija
		18	Datum
		19	Mjesto
		20	Oznaka izjave o sukladnosti
		21	Dodatak za proizvod
		22	Šifra proizvoda / kataloški broj
		23	Opis proizvoda ili inačica proizvoda
		24	Razvrstavanje rizika
		25	Osnovna jedinstvena identifikacija proizvoda-identifikator proizvoda (UDI-DI)
		26	Norme / Zajednička specifikacija (zajedničke specifikacije)

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		27	Norma / Broj zajedničke specifikacije
		28	Namjena: prijevodi na europske jezike
		29	Jezik

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Language[29]	Code	No.	Translated Terms
Czech:	**CZ**	1	EVROPSKÉ PROHLÁŠENÍ O SHODĚ
		2	Prohlášení potvrzuje, že níže uvedený výrobek splňuje nařízení 2017/745 [případně doplňte další příslušné evropské právní předpisy], a je vydáno na výhradní zodpovědnost [oficiální název výrobce]
		3	Název výrobce
		4	Adresa místa podnikání
		5	Jediné registrační číslo
		6	Oprávněný zástupce pro Evropu
		7	Adresa místa podnikání
		8	Název výrobku: (kód výrobku / katalogové číslo viz přiložený soupis)
		9	Určené použití: Viz tabulka pro další jazyky
		10	Postup posuzování shody (příloha)
		11	Název oznámeného subjektu
		12	Číslo oznámeného subjektu
		13	Osvědčení o ověření
		14	Podepsáno jménem [oficiální název výrobce]
		15	Podpis
		16	Jméno
		17	Pozice
		18	Datum
		19	Místo
		20	Prohlášení o shodě – reference
		21	Soupis výrobků
		22	Kód výrobku / katalogové číslo
		23	Popis výrobku nebo varianta výrobku
		24	Klasifikace rizik
		25	Základní UDI-DI
		26	Normy / společné specifikace
		27	Číslo normy / společné specifikace

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		28	Zamýšlené použití: překlad do evropských jazyků
		29	Jazyk

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Language[29]	Code	No.	Translated Terms
Danish:	**DK**	1	EUROPÆISK OVERENSSTEMMELSESERKLÆRING
		2	Erklæringen bekræfter, at produkterne angivet herunder overholder: Forordning 2017/745, [indsæt anden gældende europæisk lovgivning hvis relevant] og er udstedt med eneansvar for [Juridisk fabrikantnavn]
		3	Fabrikantens navn
		4	Virksomhedsadresse
		5	Individuelt registreringsnummer (Single Registration Number, SRN)
		6	Autoriseret europæisk repræsentant
		7	Virksomhedsadresse
		8	Produktnavn: (se vedlagte bilag for produktkoder/katalognumre)
		9	Tilsigtet brug: Se tabel for andre sprog
		10	Procedure for overensstemmelsesvurdering (bilag)
		11	Bemyndiget organ, navn
		12	Bemyndiget organ, nummer
		13	Verifikationscertifikat(er)
		14	Underskrevet på vegne af [Juridisk fabrikantnavn]
		15	Underskrift
		16	Navn
		17	Position
		18	Dato
		19	Placering
		20	Overensstemmelseserklæring, reference
		21	Produktbilag
		22	Produktkode/katalognummer
		23	Produktbeskrivelse eller produktvariant
		24	Risikoklasse
		25	Grundlæggende UDI-DI
		26	Standarder/almindelig(e) specifikation(er)
		27	Standard/almindeligt specifikationsnummer

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		28	Tilsigtet brug: Oversættelser på europæiske sprog
		29	Sprog

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Language[29]	Code	No.	Translated Terms
Dutch:	**NL**	1	EUROPESE CONFORMITEITSVERKLARING
		2	Deze verklaring bevestigt dat het hieronder vermelde product voldoet aan: Verordening 2017/745, [andere relevante Europese wetgeving invoegen indien van toepassing] en wordt verstrekt onder de exclusieve verantwoordelijkheid van [wettige naam van fabrikant]
		3	Naam van fabrikant
		4	Bedrijfsadres
		5	SRN (single registration number: afzonderlijk registratienummer)
		6	Geautoriseerde vertegenwoordiger voor Europa
		7	Bedrijfsadres
		8	Productnaam: (zie bijgevoegd aanhangsel voor productcodes/catalogusnummers)
		9	Beoogd gebruik: Zie tabel voor andere talen
		10	Procedure voor conformiteitsbeoordeling (bijlage)
		11	Naam van aanmeldingsinstantie
		12	Nummer van aanmeldingsinstantie
		13	Verificatiecertificaat/-certificaten
		14	Ondertekend namens [wettige naam van fabrikant]
		15	Handtekening
		16	Naam
		17	Functie
		18	Datum
		19	Plaats
		20	Referentie conformiteitsverklaring
		21	Productschema
		22	Productcode/catalogusnummer
		23	Productbeschrijving of productvariant
		24	Risicoclassificatie
		25	Basis UDI-DI

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		26	Standaarden/Algemene specificatie(s)
		27	Standaard/Algemeen specificatienummer
		28	Beoogd gebruik: vertalingen in Europese talen
		29	Taal

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Language[29]	Code	No.	Translated Terms
Estonian:	**EE**	1	EUROOPA VASTAVUSDEKLARATSIOON
		2	Selle deklaratsiooniga kinnitame allpool loetletud toote vastavust: määrusele 2017/745 [sisestage muu Euroopa õigusakt, kui on kohaldatav] ning see väljastatakse [seadusliku tootja nimi] ainuvastutusel
		3	Tootja nimi
		4	Registreeritud aadress
		5	Unikaalne registreerimisnumber (SRN)
		6	Volitatud esindaja Euroopas
		7	Registreeritud aadress
		8	Toote nimetus: (tootekoode/kataloginumbreid vt lisatud tabelist)
		9	Ettenähtud kasutusotstarve: Teisi keeli vt tabelist
		10	Vastavushindamise protseduur (lisa)
		11	Teavitatud asutuse nimetus
		12	Teavitatud asutuse number
		13	Kinnitussertifikaat/-sertifikaadid
		14	Allkirjastanud [seadusliku tootja nimi]
		15	Allkiri
		16	Nimi
		17	Ametikoht
		18	Kuupäev
		19	Asukoht
		20	Vastavusdeklaratsiooni viide
		21	Toote tabel
		22	Tootekood/kataloginumber
		23	Toote kirjeldus või toote variant
		24	Riski klassifikatsioon
		25	Põhiline UDI-DI
		26	Standardid / ühtsed tehnilised tingimused

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		27	Standardi / ühtsete tehniliste tingimuste number
		28	Ettenähtud kasutusotstarve Tõlked Euroopa keeltesse
		29	Keel

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Language[29]	Code	No.	Translated Terms
Finnish:	**FI**	1	EUROOPPALAINEN VAATIMUSTENMUKAISUUSVAKUUTUS
		2	Vakuutuksella vahvistetaan, että jäljempänä mainittu tuote täyttää: Asetuksen 2017/745, [tähän tulee lisätä muu asiaan liittyvä eurooppalainen lainsäädäntö sikäli kuin sitä on] mukaiset vaatimukset, ja annetusta vakuutuksesta vastuussa on yksinomaan [laillisen valmistajan nimi]
		3	Valmistajan nimi
		4	Toimipaikan osoite
		5	Rekisterinumero (SRN)
		6	Eurooppalainen valtuutettu edustaja
		7	Toimipaikan osoite
		8	Tuotteen nimi: (ks. liitteestä tuotekoodit/luettelonumerot)
		9	Käyttötarkoitus: Taulukossa esitetään muut kieliversiot
		10	Vaatimustenmukaisuuden arviointimenettely (Liite)
		11	Ilmoitetun laitoksen nimi
		12	Ilmoitetun laitoksen numero
		13	Tarkastustodistus (-todistukset)
		14	Allekirjoitettu puolesta [laillisen valmistajan nimi]
		15	Allekirjoitus
		16	Nimi
		17	Asema
		18	Päiväys
		19	Paikka
		20	Vaatimustenmukaisuusvakuutuksen viite
		21	Tuoteluettelo
		22	Tuotekoodi / Luettelonumero
		23	Tuotekuvaus tai tuotevariantti
		24	Riskiluokitus
		25	Perus-UDI-DI-tunniste

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		26	Standardit / Yhteinen eritelmä (tai monikossa)
		27	Standardin/yhteisen eritelmän numero
		28	Käyttötarkoitus Käännökset Euroopan kielillä
		29	Kieli

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Language[29]	Code	No.	Translated Terms
French:	**FR**	1	DÉCLARATION DE CONFORMITÉ EUROPÉENNE
		2	La déclaration confirme que le produit repris ci-dessous est conforme au : Règlement (UE) 2017/745 [insérer au besoin toute autre législation européenne pertinente] et est publiée sous la seule responsabilité de Nom du fabricant légal
		3	Nom du fabricant
		4	Adresse professionnelle
		5	Numéro d'enregistrement unique
		6	Mandataire établi dans l'UE
		7	Adresse professionnelle
		8	Nom du produit : (voir l'annexe jointe pour les codes de produit/références catalogue)
		9	Usage prévu : Voir le tableau pour les autres langues
		10	Procédure d'évaluation de la conformité (Annexe)
		11	Nom de l'organisme notifié
		12	N° de l'organisme notifié
		13	Certificat(s) de vérification
		14	Signé au nom de Nom du fabricant légal
		15	Signature
		16	Nom
		17	Poste
		18	Date
		19	Adresse
		20	Référence de la déclaration de conformité
		21	Annexe de produit
		22	Code du produit / Référence catalogue du produit
		23	Description du produit ou variante du produit
		24	Classe de risque
		25	Identifiant « dispositif » IUD (IUD-ID)

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		26	Normes / Spécification(s) commune(s)
		27	N° de la norme/spécification commune
		28	Usage prévu : traduction dans des langues européennes
		29	Langue

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Language[29]	Code	No.	Translated Terms
German	**DE**	1	EUROPÄISCHE KONFORMITÄTSERKLÄRUNG
		2	Mit dieser Erklärung wird bestätigt, dass das unten aufgeführte Produkt den folgenden Anforderungen entspricht: Verordnungen 2017/745, [ggf. andere einschlägige europäische Rechtsvorschriften einfügen]. Die alleinige Verantwortung für die Ausstellung dieser Konformitätserklärung trägt [Name des Herstellers]
		3	Name des Herstellers
		4	Geschäftsadresse
		5	Einmalige Registrierungsnummer (SRN)
		6	Europäischer Bevollmächtigter
		7	Geschäftsadresse
		8	Produktname: (Produktcodes/Katalognummern siehe beigefügtes Verzeichnis)
		9	Verwendungszweck: Andere Sprachen siehe Tabelle
		10	Konformitätsbewertungsverfahren (Anhang)
		11	Name der benannten Stelle
		12	Nummer der benannten Stelle
		13	Prüfzertifikat(e)
		14	Unterzeichnet im Auftrag von Name des Herstellers
		15	Unterschrift
		16	Name
		17	Position
		18	Datum
		19	Standort
		20	Konformitätserklärung – Referenz
		21	Produktverzeichnis
		22	Produktcode/Katalognummer
		23	Produktbeschreibung oder Produktvariante
		24	Risikoklassifizierung
		25	Basis-UDI-DI

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		26	Normen/Gemeinsame Spezifikation(en)
		27	Nummer der Norm/Gemeinsamen Spezifikation
		28	Verwendungszweck: Übersetzung in europäische Sprachen
		29	Sprache

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Language[29]	Code	No.	Translated Terms
Greek:	**GR**	1	ΕΥΡΩΠΑΪΚΗ ΔΗΛΩΣΗ ΣΥΜΜΟΡΦΩΣΗΣ
		2	Η δήλωση επιβεβαιώνει ότι το προϊόν που αναφέρεται παρακάτω πληροί: τους κανονισμούς 2017/745, [συμπληρώστε άλλη σχετική ευρωπαϊκή νομοθεσία ανάλογα με την περίπτωση] και εκδίδεται υπό την αποκλειστική ευθύνη του [επωνυμία νόμιμου κατασκευαστή]
		3	Επωνυμία κατασκευαστή
		4	Διεύθυνση επιχείρησης
		5	Ενιαίος αριθμός καταχώρισης (SRN)
		6	Εξουσιοδοτημένος αντιπρόσωπος στην Ευρώπη
		7	Διεύθυνση επιχείρησης
		8	Ονομασία προϊόντος: (βλ. συνημμένο παράρτημα κωδικών προϊόντων/αριθμών καταλόγου)
		9	Προβλεπόμενη χρήση: βλ. πίνακα για άλλες γλώσσες
		10	Διαδικασία εκτίμησης της συμμόρφωσης (παράρτημα)
		11	Επωνυμία κοινοποιημένου οργανισμού
		12	Αριθμός κοινοποιημένου οργανισμού
		13	Πιστοποιητικό(ά) επαλήθευσης
		14	Υπογραφή εξ ονόματος του [επωνυμία νόμιμου κατασκευαστή]
		15	Υπογραφή
		16	Ονοματεπώνυμο
		17	Τίτλος
		18	Ημερομηνία
		19	Τοποθεσία
		20	Αναφορά δήλωσης συμμόρφωσης
		21	Παράρτημα προϊόντων
		22	Κωδικός προϊόντος/Αριθμός καταλόγου
		23	Περιγραφή προϊόντος ή παραλλαγή προϊόντος
		24	Ταξινόμηση κινδύνου
		25	Βασικό UDI-DI
		26	Πρότυπα/Κοινή(ές) προδιαγραφή(ές)
		27	Αριθμός προτύπου/κοινής προδιαγραφής

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		28	Προβλεπόμενη χρήση: μεταφράσεις σε ευρωπαϊκές γλώσσες
		29	Γλώσσα

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Language[29]	Code	No.	Translated Terms
Hungarian:	**HU**	1	EURÓPAI MEGFELELŐSÉGI NYILATKOZAT
		2	A nyilatkozat megerősíti, hogy az alább felsorolt termék megfelel a következőknek: A 2017/745 rendeletek, [értelemszerűen illessze be ide az egyéb fontos európai jogszabályokat], és kiadása a gyártó hivatalos neve kizárólagos felelősségére történik
		3	A gyártó neve
		4	Székhelye
		5	Egyedüli nyilvántartási szám (SRN)
		6	Meghatalmazott európai képviselő
		7	Székhelye
		8	A termék neve: (lásd a mellékelt listát a termékkódokat/katalógusszámokat illetően)
		9	Rendeltetésszerű használat: Az egyéb nyelveket lásd a táblázatban
		10	Megfelelőségértékelési eljárás (melléklet)
		11	Az értesített testület neve
		12	Az értesített testület száma
		13	Hitelesítési tanúsítvány(ok)
		14	Aláírva a gyártó hivatalos neve nevében
		15	Aláírás
		16	Név
		17	Beosztás
		18	Dátum
		19	Hely
		20	A megfelelőségi nyilatkozat hivatkozása
		21	Terméklista
		22	Termékkód/katalógusszám
		23	A termék leírása vagy termékváltozat
		24	Kockázatbesorolás
		25	Alap UDI-DI
		26	Szabványok/gyakori előírás(ok)
		27	A szabvány/gyakori előírás száma

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		28	A rendeltetésszerű használat európai nyelvre történt fordítása
		29	Nyelv

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Language[29]	Code	No.	Translated Terms
Italian:	**IT**	1	DICHIARAZIONE DI CONFORMITÀ EUROPEA
		2	La dichiarazione conferma che il prodotto menzionato di seguito è conforme a: Regolamento 2017/745, [inserire altre normative europee pertinenti per quanto applicabile], ed è rilasciata sotto l'esclusiva responsabilità del fabbricante legale
		3	Nome del fabbricante
		4	Indirizzo aziendale
		5	Numero di registrazione unico (Single Registration Number, SRN)
		6	Rappresentante europeo autorizzato
		7	Indirizzo aziendale
		8	Nome del prodotto: (vedere il prospetto allegato per i codici di prodotto/numeri di catalogo)
		9	Uso previsto: vedere la tabella per le altre lingue
		10	Procedura di valutazione di conformità (Allegato)
		11	Nome dell'organismo notificato
		12	Numero dell'organismo notificato
		13	Certificazione/i di verifica
		14	Firmato in nome e per conto di (nome del fabbricante legale)
		15	Firma
		16	Nome
		17	Posizione professionale
		18	Data
		19	Sede
		20	Riferimento per la Dichiarazione di conformità
		21	Prospetto prodotti
		22	Codice prodotto/Numero di catalogo
		23	Descrizione del prodotto o variante di prodotto
		24	Classificazione del rischio
		25	Codice UDI-DI
		26	Norme/Specifiche comuni
		27	Numero norma/specifica comune

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		28	Uso previsto: traduzioni nelle lingue europee
		29	Lingua

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Language[29]	Code	No.	Translated Terms
Latvian:	**LV**	1	EIROPAS ATBILSTĪBAS DEKLARĀCIJA
		2	Deklarācija apliecina, ka tālāk norādītais produkts atbilst: Regulām 2017/745, [ievietojiet citus atbilstošus Eiropas tiesību aktus, kā nepieciešams], un tā ir izsniegta tikai uz [ražotāja juridiskais nosaukums] atbildību
		3	Ražotāja nosaukums
		4	Uzņēmuma adrese
		5	Vienotais reģistrācijas numurs (VRN)
		6	Pilnvarotais pārstāvis Eiropā
		7	Uzņēmuma adrese
		8	Produkta nosaukums: (produkta kodus/kataloga numurus skatīt pievienotajā pielikumā)
		9	Paredzētā lietošana: informāciju par citām valodām skatīt tabulā
		10	Atbilstības novērtēšanas procedūra (Pielikums)
		11	Paziņotās struktūras nosaukums
		12	Paziņotās struktūras numurs
		13	Pārbaudes sertifikāts(-i)
		14	Parakstīts [ražotāja juridiskais nosaukums] vārdā
		15	Paraksts
		16	Vārds, uzvārds
		17	Amats
		18	Datums
		19	Vieta
		20	Atbilstības deklarācijas atsauce
		21	Produkta pielikums
		22	Produkta kods/kataloga numurs
		23	Produkta apraksts vai produkta variants
		24	Riska klasifikācija
		25	Pamata UDI-DI
		26	Standarti/vispārīgā(-s) specifikācija(-s)
		27	Standarts/vispārīgās specifikācijas numurs
		28	Paredzētā lietošana: tulkojumi Eiropas valodās

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		29	Valoda

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Language[29]	Code	No.	Translated Terms
Lithuanian:	**LT**	1	Europos Atitikties Deklaracija
		2	Delaracija patvirtina kad toliau išvardyti produktai atitinka: Reglamentą 2017/745, [įterpti kitus taikytinus Europos teisės aktus] ir už jo išdavimą yra visiškai atsakingas [legalus gamintojo vardas].
		3	Gamintojo vardas
		4	Verslo adresas
		5	Bendras Registracijos Numeris (BRN)
		6	Europos įgaliotasis atstovas
		7	Verslo adresas
		8	Produkto vardas: (produktų kodus / katalogo numerius žiūrėkite pridedamame tvarkaraštyje)
		9	Paskirtis: kitomis kalbomis žiūrėkite lentelę
		10	Atitikties įvertinimo procedūra (priedas)
		11	Notifikuotosios įstaigos vardas
		12	Notifikuotosios įstaigos numeris
		13	Patvirtinimo Pažymėjimas (-ai)
		14	Pasirašyta (legalaus gamintojo vardas) vardu
		15	Parašas
		16	Vardas
		17	Pozicija
		18	Data
		19	Vieta
		20	Atitikties Deklaracijos Nuoroda
		21	Produkto grafikas
		22	Produkto Kodas/ Katalogo numeris
		23	Produkto Apibūdinimas arba Produkto Variantas
		24	Rizikos Klasifikacija
		25	Pagrindinis UDI
		26	Standartai / Bendroji specifikacija (-os)
		27	Standartinis / Bendrasis specifikacijos numeris
		28	Europos kalbų vertimas pagal paskirtį

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		29	Kalba

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Language[29]	Code	No.	Translated Terms
Polish:	**PO**	1	EUROPEJSKA DEKLARACJA ZGODNOŚCI
		2	Deklaracja potwierdza, że wymieniony poniżej produkt spełnia wymagania: Rozporządzenia 2017/745 [w razie potrzeby wstawić inne stosowne przepisy europejskie] i jest wydawana na wyłączną odpowiedzialność Nazwa producenta
		3	Nazwa producenta
		4	Adres firmy
		5	Niepowtarzalny numer rejestracyjny (SRN)
		6	Upoważniony przedstawiciel w Unii Europejskiej
		7	Adres firmy
		8	Nazwa produktu: (kody produktów / numery katalogowe zawiera załączony wykaz)
		9	Przeznaczenie: Tekst w innych językach znajduje się w tabeli
		10	Procedura oceny zgodności (załącznik)
		11	Nazwa jednostki notyfikowanej
		12	Numer jednostki notyfikowanej
		13	Certyfikaty weryfikacji
		14	Podpisano w imieniu Nazwa producenta
		15	Podpis
		16	Imię i nazwisko
		17	Stanowisko
		18	Data
		19	Miejsce
		20	Numer referencyjny deklaracji zgodności
		21	Wykaz produktów
		22	Kod produktu / numer katalogowy
		23	Opis produktu lub wariant produktu
		24	Klasyfikacja ryzyka
		25	Kod Basic UDI-DI
		26	Normy / wspólne specyfikacje
		27	Numer normy / wspólnej specyfikacji

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		28	Tłumaczenia tekstu dotyczącego przeznaczenia produktu na języki europejskie
		29	Język

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Language[29]	Code	No.	Translated Terms
Portuguese:	**PT**	1	DECLARAÇÃO DE CONFORMIDADE EUROPEIA
		2	A declaração confirma que os produtos listados abaixo cumprem: Regulamentação 2017/745, [inserir outra legislação europeia relevante, conforme aplicável] e é emitida sob a responsabilidade única do [Nome legal do fabricante]
		3	Nome do fabricante
		4	Endereço da empresa
		5	Número único de registo (NUR)
		6	Representante Europeu Autorizado
		7	Endereço da empresa
		8	Nome do produto: (consulte o anexo quanto a códigos de produtos/números de catálogo)
		9	Finalidade: Consulte a tabela para outros idiomas
		10	Procedimento de avaliação de conformidade (Anexo)
		11	Nome do organismo notificado
		12	Número do organismo notificado
		13	Certificado(s) de verificação
		14	Assinado em nome de [Nome legal do fabricante]
		15	Assinatura
		16	Nome
		17	Cargo
		18	Data
		19	Localização
		20	Referência de Declaração de conformidade
		21	Anexo do produto
		22	Código de produto / Número de catálogo
		23	Descrição do produto ou variante do produto
		24	Classificação de risco
		25	UDI-DI básico
		26	Normas / Especificação(ões) comum(ns)
		27	Normas/Número de especificação comum

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		28	Traduções da Finalidade para idiomas europeus
		29	Idioma

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Language[29]	Code	No.	Translated Terms
Romanian:	**RO**	1	DECLARAȚIE DE CONFORMITATE EUROPEANĂ
		2	Declarația confirmă faptul că produsul specificat mai jos respectă: Regulamentul 2017/745, [introduceți ale acte legislative europene relevante, după caz] și este emis pe propria răspundere a Denumirea juridică a producătorului
		3	Denumirea producătorului
		4	Sediul social
		5	Număr unic de înregistrare (SRN)
		6	Reprezentant european autorizat
		7	Sediul social
		8	Denumirea produsului: (consultați anexa atașată pentru codurile de produs/numerele de catalog)
		9	Utilizare preconizată: consultați tabelul pentru alte limbi
		10	Procedura de evaluare a conformității (Anexă)
		11	Denumirea organismului notificat
		12	Numărul organismului notificat
		13	Certificat(e) de verificare
		14	Semnat în numele Denumirea juridică a producătorului
		15	Semnătură
		16	Nume
		17	Funcție
		18	Dată
		19	Loc
		20	Referință pentru declarația de conformitate
		21	Anexa produsului
		22	Cod produs / Număr de catalog
		23	Descrierea produsului sau varianta produsului
		24	Clasificarea riscurilor
		25	UDI-DI de bază
		26	Standarde / Specificație(i) comună(e)
		27	Standard / Număr de specificație comună
		28	Utilizare preconizată: traduceri în limbile europene

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		29	Limbă

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Language[29]	Code	No.	Translated Terms
Slovak:	**SK**	1	VYHLÁSENIE O ZHODE EÚ
		2	Vyhlásenie potvrdzuje, že nižšie uvedený produkt spĺňa: nariadenia 2017/745, [vložiť ďalšie príslušné právne predpisy EÚ] a vydáva sa s výhradnou zodpovednosťou výrobcu s registrovaným názvom
		3	Názov výrobcu
		4	Sídlo spoločnosti
		5	Jediné registračné číslo (SRN)
		6	Oprávnený zástupca pre EÚ
		7	Sídlo spoločnosti
		8	Názov produktu: (pozri priložený dodatok s kódmi výrobkov/katalógovými číslami)
		9	Plánované použitie: Ďalšie jazyky nájdete v tabuľke
		10	Postup posudzovania zhody (príloha)
		11	Názov notifikovaného orgánu
		12	Číslo notifikovaného orgánu
		13	Overovacie certifikáty
		14	Podpísaný v mene výrobcu s registrovaným názvom
		15	Podpis
		16	Meno
		17	Pozícia
		18	Dátum
		19	Miesto
		20	Odkaz na vyhlásenie o zhode
		21	Tabuľka výrobkov
		22	Kód výrobku / katalógové číslo
		23	Popis produktu alebo variant produktu
		24	Klasifikácia rizika
		25	Základný identifikátor UDI-DI
		26	Normy / spoločné špecifikácie
		27	Číslo normy / spoločnej špecifikácie
		28	Plánované použitie prekladov z jazykov EÚ

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		29	Jazyk

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

Language[29]	Code	No.	Translated Terms
Slovenian:	**SL**	1	EVROPSKA IZJAVA O SKLADNOSTI
		2	Izjava potrjuje, da spodaj navedeni izdelek ustreza: Uredbi 2017/745 [vstavite drugo zadevno evropsko zakonodajo, kakor je primerno], in je izdana na lastno odgovornost [Ime zakonitega proizvajalca]
		3	Ime proizvajalca
		4	Poslovni naslov
		5	Enotna registrska številka (SRN)
		6	Pooblaščeni zastopnik za Evropo
		7	Poslovni naslov
		8	Ime izdelka: (glejte priložen dodatek s kodami/katalоškimi številkami izdelkov)
		9	Predvidena uporaba: Za druge jezike glejte preglednico
		10	Postopek ugotavljanja skladnosti (Priloga)
		11	Ime priglašenega organa
		12	Številka priglašenega organa
		13	Potrdilo(-a) o verifikaciji
		14	Podpisano v imenu Ime zakonitega proizvajalca
		15	Podpis
		16	Ime
		17	Delovno mesto
		18	Datum
		19	Mesto
		20	Referenca Izjave o skladnosti
		21	Dodatek z izdelki
		22	Koda/kataloška številka izdelka
		23	Opis izdelka ali različica izdelka
		24	Razvrščanje v razred tveganja
		25	Osnovni UDI-DI
		26	Standardi/splošne specifikacije
		27	Standardna/splošna številka specifikacije
		28	Prevodi predvidene uporabe v evropske jezike

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		29	Jezik

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Language[29]	Code	No.	Translated Terms
Spanish:	**ES**	1	DECLARACIÓN UE DE CONFORMIDAD
		2	Esta declaración confirma que el producto indicado a continuación cumple con lo estipulado en el Reglamento (UE) 2017/745, [incluir otras normativas europeas pertinentes que sean de aplicación] y se publica bajo la exclusiva responsabilidad de [Nombre legal del fabricante]
		3	Nombre del fabricante
		4	Domicilio social
		5	Número de registro único (SRN)
		6	Representante autorizado en Europa
		7	Domicilio social
		8	Nombre del producto: (véase el apéndice para comprobar los códigos/números de catálogo de los productos)
		9	Uso previsto: véase la tabla para consultar otros idiomas
		10	Procedimiento de evaluación de la conformidad (anexo)
		11	Nombre del organismo notificado
		12	Número del organismo notificado
		13	Certificados de verificación
		14	Firmado en nombre de [Nombre legal del fabricante]
		15	Firma
		16	Nombre
		17	Puesto
		18	Fecha
		19	Ubicación
		20	Referencia de la declaración de conformidad
		21	Apéndice del producto
		22	Código/número de catálogo del producto
		23	Descripción o variante del producto
		24	Clasificación del riesgo
		25	UDI-DI básica
		26	Normas/especificaciones comunes
		27	Número de norma/especificación común

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		28	Uso previsto: traducciones a idiomas europeos
		29	Idioma

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Language[29]	Code	No.	Translated Terms
Swedish:	**SE**	1	EUROPEISK FÖRSÄKRAN OM ÖVERENSSTÄMMELSE
		2	Denna försäkran bekräftar att produkten som anges nedan uppfyller: kraven i förordning 2017/745, [infoga annan relevant Europeisk lagstiftning om tillämpligt] och utfärdas på eget ansvar av [tillverkarens namn]
		3	Tillverkarens namn
		4	Företagsadress
		5	Eudamed-registreringsnummer (SRN)
		6	Auktoriserad representant i Europa
		7	Företagsadress
		8	Produktnamn: (se den bifogade översikten för produktkoder/katalognummer)
		9	Avsedd användning: Se tabellen för andra språk
		10	Procedur för bedömning av överensstämmelse (bilaga)
		11	Anmälda organets namn
		12	Anmälda organets identifikationsnummer
		13	Verifieringscertifikat
		14	Undertecknat på [tillverkarens namn]:s vägnar
		15	Underskrift
		16	Namn
		17	Befattning
		18	Datum
		19	Placering
		20	Referens för försäkran om överensstämmelse
		21	Produktöversikt
		22	Produktkod/katalognummer
		23	Produktbeskrivning eller produktvariant
		24	Riskklassificering
		25	Grundläggande UDI-DI
		26	Standarder/gemensam(ma) specifikation(er)
		27	Standard/gemensamt specifikationsnummer
		28	Avsedd användning av översättningar till europeiska språk

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		29	Språk

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