

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

T + 44 (0) 1482 225181
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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: | CICA-CARE |
| Intended Use⁹ | <p><u>For Product Codes 66250704, 66250705, 66250706, 66250707:</u></p> <p>CICA-CARE gel sheet is designed for long term use:</p> <ul style="list-style-type: none"> • In the management of both existing and new hypertrophic scars and keloids. • As a prophylactic therapy on healed wounds to help to prevent hypertrophic scarring and keloids. <p><u>For Product Codes 66000702, 66030702, 66320703, 66801535, 66801854:</u></p> <p>CICA-CARE gel sheet is designed for:</p> <ul style="list-style-type: none"> • In the management of both existing and new red, raised scars (hypertrophic/keloidal) and as a preventative therapy on healed wounds to help prevent red, raised scars. |
| Conformity Assessment Procedure (Annex)¹⁰ | Annex XI Part A (Production Quality Assurance) |
| Notified Body Name¹¹ | BSI Group The Netherlands B.V |
| Notified Body Number¹² | No. 2797 |
| Verification Certificate(s)¹³ | MDR 737173 |


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| Signed on behalf of Smith & Nephew Medical Limited ¹⁴ | |
|--|---|
| Signature¹⁵ | <p>DocuSigned by:</p>  <p>Signer Name: Andrew Daghli Signing Reason: I approve this document Signing Time: 19-Jul-2023 18:03:02 BST 303C90DE917A4F32AA0ABF5C275816BC</p> |
| Name¹⁶ | Andrew Daghli |
| Position¹⁷ | Senior Regulatory Affairs Specialist |
| Date¹⁸ | 19-Jul-2023 18:03:04 BST |
| Location¹⁹ | Hull, UK |
| Declaration of Conformity Reference²⁰ | DOC-WMTF-023/V3 |

| Product Schedule ²¹ | | | |
|---|--|-----------------------------------|-------------------------|
| Product Code / Catalogue Number ²² | Product Description or Product Variant ²³ | Risk Classification ²⁴ | Basic UDI ²⁵ |
| 66000702 | 6cm x 12cm / pack of 1 | IIa | 5000223SN000113R2 |
| 66030702 | 6cm x 12 cm / pack of 1 | IIa | 5000223SN000113R2 |
| 66320703 | 6cm x 12 cm / pack of 5 | IIa | 5000223SN000113R2 |
| 66250704 | 6cm x 12cm / pack of 1 | IIa | 5000223SN000113R2 |
| 66250705 | 6cm x 12 cm / pack of 40 | IIa | 5000223SN000113R2 |
| 66250706 | 15cm x 12cm / pack of 1 | IIa | 5000223SN000113R2 |
| 66250707 | 15cm x 12cm / pack of 10 | IIa | 5000223SN000113R2 |
| 66801535 | 6cm x 12cm / pack of 1 | IIa | 5000223SN000113R2 |
| 66801854 | 3cm x 12cm / pack of 1 | IIa | 5000223SN000113R2 |

| 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 |
| ISO 10993-1:2020 |
| EN ISO 10993-2:2022 |

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| |
|--------------------------------|
| EN ISO 10993-5:2009 |
| EN ISO 10993-10:2021 |
| EN ISO 10993-12:2021 |
| EN ISO 10993-18:2020/AMD1:2022 |
| EN ISO 10993-23:2021 |
| EN ISO 20417:2021 |
| EN 62366-1:2015/AMD1:2020 |
| EN ISO 14644-1:2015 |
| ISTA 2A:2011 |

Intended Use European Language Translations²⁷:

| Language ²⁸ | | Code | Intended Use |
|------------------------|----------------|------|--|
| EN | Local | | |
| Bulgarian | български език | BG | <ol style="list-style-type: none"> при лечението както на съществуващи, така и на нови хипертрофични белези и келоиди, както и като профилактична терапия на зараснали рани, за да помогне за предотвратяване на хипертрофични белези и келоиди. |
| Croatian | Hrvatski | HR | <ol style="list-style-type: none"> u liječenju postojećih i novih hipertrofičnih ožiljaka i keloida te kao profilaktička terapija na zacjeljenim ranama radi sprečavanja stvaranja hipertrofičnih ožiljaka i keloida. |
| Czech | Český Jazyk | CZ | <ol style="list-style-type: none"> při léčbě existujících i nových hypertrofických jizev a keloidů a jako profylaktická terapie na zahojených ranách, která pomáhá zabránit hypertrofickým zjizvením a keloidům |
| Danish | Dansk | DK | <ol style="list-style-type: none"> i behandlingen af både eksisterende og nye hypertrofiske ar og keloiddannelse, og som en profylaktisk behandling på heledede sår til at hjælpe med at forebygge hypertrofisk ardannelse og keloider. |
| Dutch | Nederlands | NL | <ol style="list-style-type: none"> therapie van bestaande en nieuwe hypertrofische littekens of keloiden, het kan ook als profylactische therapie op genezen wonden worden gebruikt om verheven littekenweefsel en keloiden te helpen voorkomen. |
| Estonian | Eesti | EE | <ol style="list-style-type: none"> Nii olemasolevate kui ka uute hüpertroofiliste armide ja keloidide ravis ja Profülaktiliseks raviks paranenud haavadele, et aidata vältida hüpertroofilist armistumist ja keloide. |
| Finnish | Suomi | FI | <ol style="list-style-type: none"> Vanhojen sekä uusien liikakasvuisten arprien ja keloidien hoitoon Parantuneiden haavojen suojaamiseen estämään arprien sekä keloidien liikakasvua. |
| French | Français | FR | <ol style="list-style-type: none"> dans les soins des cicatrices hypertrophiques ou chéloïdes anciennes ou récentes et en traitement prophylactique sur plaies cicatrisées pour prévenir la formation de cicatrices hypertrophiques et chéloïdes |
| German | Deutsch | DE | <ol style="list-style-type: none"> der Therapie von bestehenden oder neu ausgebildeten hypertrophen oder kelloidalen Narben und; als Prophylaxe-Maßnahme bei abgeheilten Wunden, um die Ausbildung von hypertrophen oder kelloidalen Narben zu |

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| | | | vermeiden. |
|------------|-------------|----|--|
| Greek | Ελληνικά | GR | <ol style="list-style-type: none"> 1. Για την αντιμετώπιση ήδη υπαρχόντων και νέων υπερτροφικών ουλών και χηλοειδών. 2. Σαν θεραπεία πρόληψης σε τραύματα που έχουν επουλωθεί με σκοπό την πρόληψη δημιουργίας υπερτροφικών ουλών και χηλοειδών. |
| Hungarian | Magyar | HU | <ol style="list-style-type: none"> 1. a meglévő és az új hipertrófiás hegek és keloidok kezeléséhez, és profilaktikus terápiaként a gyógyult sebeken a hipertrófiás hegesezés és a keloidok megelőzéséhez. |
| Italian | Italiano | IT | <ol style="list-style-type: none"> 1. nel trattamento di preesistenti o nuove cicatrici ipertrofiche e cheloidi 2. come trattamento di prevenzione su ferite guarite per prevenire cicatrici ipertrofiche e cheloidi. |
| Latvian | Latviešu | LV | <ol style="list-style-type: none"> 1. esošu un jaunu hipertrofisko rētu keloīdu kopsanai, ka arī profilaktiskai sadzījušu brūču terapijai, lai novērstu hipertrofiska rētojumā un keloīdu veidošanos. |
| Lithuanian | Lietuvių | LT | <ol style="list-style-type: none"> 1. gydanti tiek esamus, tiek naujus hipertrofinius ir keloidinius randus, ir. 2. kaip sugijusių žaizdų profilaktinė terapija, skirta padėti apsaugoti nuo hipertrofinio ir keloidinio randėjimo. |
| Norwegian | Norsk | NO | <ol style="list-style-type: none"> 1. til behandling og forebygging av både eksisterende og nye hypertrofiske og keloide arr og 2. som en profylaktisk behandling på tilhelede sår til hjelp for å forhindre hypertrofiske og kelloide arrdannelser. |
| Polish | Polski | PL | <ol style="list-style-type: none"> 1. w leczeniu istniejących i nowych blizn przerostowych i bliznowców oraz 2. jako terapia profilaktyczna zagojonych ran, zapobiegająca powstawaniu blizn przerostowych i bliznowców. |
| Portuguese | Português | PT | <ol style="list-style-type: none"> 1. No tratamento de cicatrizes hipertróficas e quelóides já existentes ou recentes e; 2. Como terapêutica profilática de feridas cicatrizadas para ajudar a prevenir a formação de cicatrizes hipertróficas e de quelóides. |
| Romanian | Română | RO | <ol style="list-style-type: none"> 1. în tratamentul cicatricilor hipertrofice și al cheloidelor atât existente, cât și noi și 2. ca terapie profilactică a plăgilor vindecate pentru a ajuta la prevenirea cicatricilor hipertrofice și a cheloidelor. |
| Slovak | Slovenčina | SK | <ol style="list-style-type: none"> 1. pri liečbe existujúcich aj nových hypertrofických jaziev a keloidov a ako profylaktická liečba zahojených rán, ktorá pomáha predchádzať vzniku hypertrofických jaziev a keloidov. |
| Slovenian | Slovenščina | SI | <ol style="list-style-type: none"> 1. pri oskrbi obstoječih in novih hipertrofičnih brazgotin in keloidov ter pri preventivnem zdravljenju zaceljenih ran za preprečevanje tvorbe hipertrofičnih brazgotin in keloidov. |
| Spanish | Español | ES | <ol style="list-style-type: none"> 1. La lámina de gel CICA-CARE está diseñada para uso temporal en: 2. El tratamiento de cicatrices existentes y de nuevas cicatrices hipertróficas y queloides. |
| Swedish | Svenska | SE | <ol style="list-style-type: none"> 1. vid behandling av både existerande och nya hypertrofiska eller keloidea ärr samt 2. som profylaktisk behandling på läkta sår för att förhindra hypertrofisk ärrbildning och keloider |

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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 | Maltese | Malti | MT |
| Appendix 16 | Polish | Polski | PL |
| Appendix 17 | Portuguese | Português | PT |
| Appendix 18 | Romanian | Română | RO |
| Appendix 19 | Slovak | Slovenčina | SK |
| Appendix 20 | Slovenian | Slovenščina | SL |
| Appendix 21 | Spanish | Español | ES |
| Appendix 22 | Swedish | Svenska | SE |

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| Appendix 1 | | | |
|----------------------|---|-------------------------|----------------|
| Language (EN) | Bulgarian (BG) | Language (Local) | български език |
| No. | Translated Term | | |
| 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 (EPN) | | |
| 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 / Каталоген 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 | Предназначение: Преводи на европейски езици | | |
| 28 | Език | | |

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| Appendix 2 | | | |
|---------------|--|------------------|----------|
| Language (EN) | Croatian (HR) | Language (Local) | Hrvatski |
| No. | Translated Term | | |
| 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 proizvođača | | |
| 5 | Jedinstveni registracijski broj (SRN) | | |
| 6 | Ovlašteni zastupnik za Europu | | |
| 7 | Adresa ovlaštenog zastupnika | | |
| 8 | Naziv proizvoda: (šifre proizvoda/kataloške brojeve potražite u priloženom dodatku) | | |
| 9 | Namjena: Vidi tablicu za ostale jezike | | |
| 10 | Postupak procjenjivanja 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 | Klasa rizika | | |
| 25 | Osnovna jedinstvena identifikacija proizvoda-identifikator proizvoda (UDI-DI) | | |
| 26 | Norme / Uobičajena specifikacija (Uobičajene specifikacije) | | |
| 27 | Namjena: prijevodi na europske jezike | | |
| 28 | Jezik | | |

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| Appendix 3 | | | |
|---------------|---|------------------|-------------|
| Language (EN) | Czech (CZ) | Language (Local) | Český Jazyk |
| No. | Translated Term | | |
| 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 příložený 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 | Zamýšlené použití: překlad do evropských jazyků | | |
| 28 | Jazyk | | |

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| Appendix 4 | | | |
|---------------|---|------------------|-------|
| Language (EN) | Danish (DK) | Language (Local) | Dansk |
| No. | Translated Term | | |
| 1 | EUROPÆISK OVERENSSTEMMELSESESKLÆRING | | |
| 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 | Tilsigtet brug: Oversættelser på europæiske sprog | | |
| 28 | Sprog | | |

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| Appendix 5 | | | |
|---------------|--|------------------|------------|
| Language (EN) | Dutch (NL) | Language (Local) | Nederlands |
| No. | Translated Term | | |
| 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 uitgegeven onder de uitsluitende verantwoordelijkheid van [wettige naam van fabrikant] | | |
| 3 | Naam van de fabrikant | | |
| 4 | Bedrijfsadres | | |
| 5 | SRN (single registration number: uniek registratienummer) | | |
| 6 | Geautoriseerde vertegenwoordiger voor Europa | | |
| 7 | Bedrijfsadres | | |
| 8 | Productnaam: (zie bijgevoegd bijlage voor productcodes/catalogusnummers) | | |
| 9 | Beoogd gebruik: Zie de tabel voor andere Europese talen | | |
| 10 | Conformiteitsbeoordelingsprocedure (bijlage) | | |
| 11 | Naam van aangemelde instantie | | |
| 12 | Nummer van aangemelde instantie | | |
| 13 | Verificatiecertificaat/-certificaten | | |
| 14 | Ondertekend namens [naam van de 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 | Beoogd gebruik: vertalingen in Europese talen |
| 28 | Taal |

| Appendix 6 | | | |
|---------------|---|------------------|-------|
| Language (EN) | Estonian (EE) | Language (Local) | Eesti |
| No. | Translated Term | | |
| 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: (tootekode/katalooginumbreid 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/katalooginumber | | |
| 23 | Toote kirjeldus või toote variant | | |
| 24 | Riski klassifikatsioon | | |
| 25 | Põhiline UDI-DI | | |
| 26 | Standardid / ühtsed tehnilised tingimused | | |
| 27 | Ettenähtud kasutusotstarve Tõlked Euroopa keeltesse | | |
| 28 | Keel | | |

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| Appendix 7 | | | |
|---------------|--|------------------|-------|
| Language (EN) | Finnish (FI) | Language (Local) | Suomi |
| No. | Translated Term | | |
| 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 | Tuotokuvaus tai tuotevariantti | | |
| 24 | Riskiluokitus | | |
| 25 | Perus-UDI-DI-tunniste | | |
| 26 | Standardit / Yhteinen eritelmä (tai monikossa) | | |
| 27 | Käyttötarkoitus Käännökset Euroopan kielillä | | |
| 28 | Kieli | | |

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| Appendix 8 | | | |
|----------------------|--|-------------------------|----------|
| Language (EN) | French (FR) | Language (Local) | Français |
| No. | Translated Term | | |
| 1 | DÉCLARATION DE CONFORMITÉ EU | | |
| 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 | Fonction du signataire | | |
| 18 | Date | | |
| 19 | Adresse | | |
| 20 | Référence de la déclaration de conformité | | |
| 21 | Information 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) | | |
| 26 | Normes / Spécification(s) commune(s) | | |
| 27 | Usage prévu : traduction dans les langues européennes | | |
| 28 | Langue | | |

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| Appendix 9 | | | |
|---------------|--|------------------|---------|
| Language (EN) | German (DE) | Language (Local) | Deutsch |
| No. | Translated Term | | |
| 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 | | |
| 26 | Normen/Gemeinsame Spezifikation(en) | | |
| 27 | Verwendungszweck: Übersetzung in europäische Sprachen | | |
| 28 | Sprache | | |

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| Appendix 10 | | | |
|---------------|--|------------------|----------|
| Language (EN) | Greek (GR) | Language (Local) | Ελληνικά |
| No. | Translated Term | | |
| 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) | | |

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| 27 | Προβλεπόμενη χρήση: μεταφράσεις σε ευρωπαϊκές γλώσσες |
| 28 | Γλώσσα |

| Appendix 11 | | | |
|---------------|--|------------------|--------|
| Language (EN) | Hungarian (HU) | Language (Local) | Magyar |
| No. | Translated Term | | |
| 1 | EURÓPAI MEGFELELŐSÉGI NYILATKOZAT | | |
| 2 | A nyilatkozat megerősíti, hogy az alább felsorolt termék megfelel a következőknek: A 2017/745 rendelet, [értelemszerűen illeszse be ide az egyéb fontos európai jogszabályokat], és kiadása a [gyártó hivatalos neve] kizárólagos felelősségére történik | | |
| 3 | A gyártó neve | | |
| 4 | Székhelye | | |
| 5 | Egyedi nyilvántartási szám (SRN) | | |
| 6 | Meghatalmazott európai képviselő | | |
| 7 | Székhelye | | |
| 8 | A termék neve: (lásd a mellékelt listát a termékkódokat/katalógusszámokat illetően) | | |
| 9 | Rendeltetészerű használat: Az egyéb nyelveket lásd a táblázatban | | |
| 10 | Megfelelőségértékelési eljárás (melléklet) | | |
| 11 | Kijelölt szervezet neve | | |
| 12 | Kijelölt szervezet 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 / általános specifikáció(k) | | |

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|----|---|
| 27 | A rendeltetészerű használat európai nyelvre történt fordítása |
| 28 | Nyelv |

| Appendix 12 | | | |
|---------------|---|------------------|----------|
| Language (EN) | Italian (IT) | Language (Local) | Italiano |
| No. | Translated Term | | |
| 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 | | |

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|----|---|
| 25 | Codice UDI-DI |
| 26 | Norme/Specifiche comuni |
| 27 | Usò previsto: traduzioni nelle lingue europee |
| 28 | Lingua |

| Appendix 13 | | | |
|---------------|---|------------------|----------|
| Language (EN) | Latvian (LV) | Language (Local) | Latviešu |
| No. | Translated Term | | |
| 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 | | |

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| 25 | Pamata UDI-DI |
| 26 | Standarti/vispārīgā(-s) specifikācija(-s) |
| 27 | Paredzētā lietošana: tulkojumi Eiropas valodās |
| 28 | Valoda |

| Appendix 14 | | | |
|---------------|---|------------------|----------|
| Language (EN) | Lithuanian (LT) | Language (Local) | Lietuvių |
| No. | Translated Term | | |
| 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 pavadinimas | | |
| 4 | Verslo adresas | | |
| 5 | Bendras Registracijos Numeris (BRN) | | |
| 6 | Europos įgaliotasis atstovas | | |
| 7 | Verslo adresas | | |
| 8 | Produkto vardas: (produktų kodus / katalogo numerius žiūrėkite priede) | | |
| 9 | Paskirtis: kitomis kalbomis žiūrėkite lentelę | | |
| 10 | Atitikties deklaracija (priedas) | | |
| 11 | Notifikuotosios įstaigos pavadinimas | | |
| 12 | Notifikuotosios įstaigos numeris | | |
| 13 | Patvirtinimo sertifikatas (-ai) | | |
| 14 | Pasirašyta (legalaus gamintojo vardas) vardu | | |
| 15 | Parašas | | |
| 16 | Vardas | | |
| 17 | Pareigos | | |
| 18 | Data | | |
| 19 | Vieta | | |
| 20 | Atitikties Deklaracijos Nuoroda | | |
| 21 | Produktų sąrašas | | |
| 22 | Produkto Kodas/ Katalogo numeris | | |
| 23 | Produkto Apibūdinimas arba Produkto Variantas | | |

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| | |
|----|---|
| 24 | Rizikos Klasifikacija |
| 25 | Pagrindinis UDI |
| 26 | Standartai / Bendroji specifikacija (-os) |
| 27 | Numatomi vartoti Europos šalių kalbų vertimai |
| 28 | Kalba |

| Appendix 15 | | | |
|---------------|---|------------------|-------|
| Language (EN) | Maltese (MT) | Language (Local) | Malti |
| No. | Translated Term | | |
| 1 | DIKJARAZZJONI EWROPEA TA' KONFORMITÁ | | |
| 2 | Id-dikjarazzjoni tikkonferma li l-prodott imniżżel hawn taħt jissodisfa: Ir-Regolamenti 2017/745, [daħħal leġiżlazzjoni Ewropea rilevanti oħra kif applikabbli] u tinħareġ taħt ir-responsabbiltà unika tal-Isem Ġuridiku tal-Manifattura | | |
| 3 | Isem tal-Manifattur | | |
| 4 | Indirizz tan-Negożju | | |
| 5 | Numru ta' Registrazzjoni Uniku (SRN) | | |
| 6 | Rappreżentant Ewropew Awtorizzat | | |
| 7 | Indirizz tan-Negożju | | |
| 8 | Isem tal-Prodott: (ara l-iskeda mehmuża għall-kodiċijiet tal-prodott/numri tal-katalgu) | | |
| 9 | Użu Maħsub: Ara t-tabella għal-lingwi l-oħrajn | | |
| 10 | Proċedura tal-Evalwazzjoni tal-Konformità (Anness) | | |
| 11 | Isem tal-Korp Notifikat | | |
| 12 | Numru tal-Korp Notifikat | | |
| 13 | Ċertifikat(i) ta' Verifika | | |
| 14 | Iffirmat f'Isem l-Isem Ġuridiku tal-Manifattura | | |
| 15 | Firma | | |
| 16 | Isem | | |
| 17 | Pożizzjoni | | |
| 18 | Data | | |
| 19 | Post | | |
| 20 | Referenza tad-Dikjarazzjoni ta' Konformità | | |
| 21 | Skeda tal-Prodott | | |
| 22 | Kodiċi tal-Prodott / Numru tal-Katalgu | | |

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| | |
|----|--|
| 23 | Deskrizzjoni tal-Prodott jew Varjant tal-Prodott |
| 24 | Klassifikazzjoni tar-Riskju |
| 25 | UDI-DI Bażiku |
| 26 | Standards / Speċifikazzjoni(jiet) Komuni |
| 27 | Użu Maħsub Traduzzjonijiet tal-Lingwi Ewropej |
| 28 | Lingwa |

| Appendix 16 | | | |
|---------------|---|------------------|--------|
| Language (EN) | Polish (PL) | Language (Local) | Polski |
| No. | Translated Term | | |
| 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 | Przewidziane używanie : 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 | | |

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|----|---|
| 22 | Kod produktu / numer katalogowy |
| 23 | Opis produktu lub wariant produktu |
| 24 | Klasyfikacja ryzyka |
| 25 | Kod Basic UDI-DI |
| 26 | Normy / wspólne specyfikacje |
| 27 | Tłumaczenia tekstu dotyczącego przeznaczenia produktu na języki europejskie |
| 28 | Język |

| Appendix 17 | | | |
|---------------|--|------------------|-----------|
| Language (EN) | Portuguese (PT) | Language (Local) | Português |
| No. | Translated Term | | |
| 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 | | |

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| | |
|----|---|
| 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 | Traduções da Finalidade para idiomas europeus |
| 28 | Idioma |

| Appendix 18 | | | |
|---------------|---|------------------|--------|
| Language (EN) | Romanian (RO) | Language (Local) | Română |
| No. | Translated Term | | |
| 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 (CUI) | | |
| 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 | | |

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|----|--|
| 19 | Locatie |
| 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 (identificator unic de dispozitiv) de bază |
| 26 | Standarde / Specificație(i) comună(e) |
| 27 | Utilizare preconizată: traduceri în limbile europene |
| 28 | Limbă |

| Appendix 19 | | | |
|---------------|---|------------------|------------|
| Language (EN) | Slovak (SK) | Language (Local) | Slovenčina |
| No. | Translated Term | | |
| 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 | | |

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|----|---|
| 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 | Plánované použitie prekladov z jazykov EÚ |
| 28 | Jazyk |

| Appendix 20 | | | |
|---------------|--|------------------|-------------|
| Language (EN) | Slovenian (SI) | Language (Local) | Slovenščina |
| No. | Translated Term | | |
| 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 | Pooblaščen zastopnik za Evropo | | |
| 7 | Poslovni naslov | | |
| 8 | Ime izdelka: (glejte priložen dodatek s kodami/kataložskimi številkami izdelkov) | | |
| 9 | Predvidena uporaba: Za druge jezike glejte preglednico | | |
| 10 | Postopek ugotavljanja skladnosti (Priloga) | | |
| 11 | Ime priglašene organa | | |
| 12 | Številka priglašene organa | | |
| 13 | Potrdilo(-a) o verifikaciji | | |
| 14 | Podpisano v imenu Ime zakonitega proizvajalca | | |
| 15 | Podpis | | |
| 16 | Ime | | |
| 17 | Delovno mesto | | |

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|----|--|
| 18 | Datum |
| 19 | Kraj |
| 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 | Prevodi predvidene uporabe v evropske jezike |
| 28 | Jezik |

| Appendix 21 | | | |
|---------------|---|------------------|---------|
| Language (EN) | Spanish (ES) | Language (Local) | Español |
| No. | Translated Term | | |
| 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] | | |

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| | |
|----|---|
| 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 | Uso previsto: traducciones a idiomas europeos |
| 28 | Idioma |

| Appendix 22 | | | |
|---------------|--|------------------|---------|
| Language (EN) | Swedish (SE) | Language (Local) | Svenska |
| No. | Translated Term | | |
| 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 | | |

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| | |
|----|---|
| 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 | Avsedd användning av översättningar till europeiska språk |
| 28 | Språk |

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