Allegato al Certificato CE n. 1668/MDD - Elenco dei Dispositivi

Annex of EC Certificate no. 1668/MDD - Device List

rev. 0 del/of **2021/03/19**

Categoria di dispositivo: Device category:	**Circuiti per foto immuno terapia** Photo immuno therapy kit
Modello/i: Model(s):	**Codici** / Codes: • **PIT-KIT** • **PIT-KIT/SD** • **PIT-KIT/LP** • **PIT-KIT/CS**
Marca / Marche: Trademark(s):	**HMC PREMEDICAL**

Allegato al Certificato CE n. 1668/MDD - Elenco dei Dispositivi

Annex of EC Certificate no. 1668/MDD - Device List

rev. 0 del/of **2021/03/19**

Categoria di dispositivo: Device category:	**Dispositivi per trasfusione e accessori** Transfusion sets and accessories
Modello/i: Model(s):	**Codice** / Code: • **MSI/xxxyyy** **dove /** where**:** **MSI = Dispositivo per trasfusione /** Device for transfusion **xxx = Caratteri numerici /** Numeric characters **yyy = Varie tipologie di componentistica /** Different combinations of components **Possibile aggiunta di max. 5 caratteri alfanumerici al fine di distinguere prodotti tra loro similari** Possible addition of max. 5 alphanumeric characters to distinguish between similar products
Marca / Marche: Trademark(s):	**HMC PREMEDICAL**

Allegato al Certificato CE n. 1668/MDD - Elenco dei Dispositivi

Annex of EC Certificate no. 1668/MDD - Device List

rev. 0 del/of **2021/03/19**

Categoria di dispositivo: Device category:	**Dispositivi per infusione e accessori – set per infusione farmaci antiblastici** Infusion sets and accessories – infusion sets for antiblastic drugs
Modello/i: Model(s):	- **Dispositivo per infusione e monitoraggio della pressione venosa centrale /** Device for infusion and monitoring of central venous pressure - **Prolunga in PVC e PE /** PVC and Polyethylene extension line - **Prolunga a spirale PVC-FREE /** PVC-free coil extension line - **Prolunga con rubinetti /** Extension line with stopcocks - **Tappi, rubinetti e transfer /** Caps, stopcocks and transfer - **Rampe e rubinetti con e senza prolunga /** Manifolds and stopcocks with and without extension line - **Sistema con camera di gocciolamento e microregolatore /** System with drip chamber and micro- regulator - **Prolunga multivia /** Multi-lumen extension line - **Deflussori, set di riempimento e accessori /** Infusion sets, filling sets and accessories - **Sistemi per angiografia /** Angiography systems - **Prolunga ad alta pressione /** High pressure extension line - **Prolunga rinforzata /** Reinforced extension line - **Rubinetti e rampe ad alta pressione /** High pressure stopcocks and manifolds **Codici** / Codes: • **MCI/xxx(y)(y)(y)(y)(y)(y)** • **01yyxxxx** • **MSI/021** • **RAL13041700x** • **26001/T** • **26002/T** • **200050** • **BS015-30** • **4894000-01** **dove /** where: **MCI = Dispositivo per infusione /** Device for infusion **xxx = può assumere i seguenti valori: da 001 a 799 /** can assume the following values: from 001 to 799 **Y = Carattere alfanumerico /** alphanumeric character **xxxx = Varianti di prodotto /** product variations **Possibile aggiunta di max. 9 caratteri alfanumerici al fine di distinguere prodotti tra loro similari** Possible addition of max. 9 alphanumeric characters to distinguish between similar products **Codici** / Codes: • **M06xxxx(y)(y)(y)(y)(y)(y)(y)(y)(y)(y)** **dove /** where: **x = carattere numerico** / numeric character **y = carattere alfanumerico** / alphanumeric character **Possibile aggiunta di max. 10 caratteri alfanumerici al fine di distinguere prodotti tra loro similari** Possible addition of max. 10 alphanumeric characters to distinguish between similar products
Marca / Marche: Trademark(s):	**HMC PREMEDICAL**

Allegato al Certificato CE n. 1668/MDD - Elenco dei Dispositivi

Annex of EC Certificate no. 1668/MDD - Device List

rev. 0 del/of **2021/03/19**

Categoria di dispositivo: Device category:	**Sistemi di drenaggio toracico e post operatorio** Thoracic drainage and post operative systems
Modello/i: Model(s):	**Set per toracentesi e paracentesi /** thoracentesis and paracentesis sets **Codici** / Codes: • **MCI/xxxTOR** • **MCI/xxxPAR** **dove /** where: **MCI = Set per toracentesi e paracentesi** / Thoracentesis and paracentesis sets **xxx = Varie tipologie di componentistica** / Different combinations of components **TOR =Set per toracentesi** / Thoracentesis set **PAR = Set per paracentesi** / Paracentesis set **Possibile aggiunta di max. 1 carattere alfanumerico al fine di distinguere prodotti tra loro similari** Possible addition of max. 1 alphanumeric digit to distinguish between similar products
Modello/i: Model(s):	**Sistemi per drenaggio toracico /** thoracic drainage systems: - **Sistemi per drenaggio toracico a 1,2 o 3 bottiglie in plastica /** Thoracic drainage systems 1,2 or 3 plastic bottle - **Sistemi per drenaggio toracico a 1 o 2 bottiglie in vetro /** Thoracic drainage systems 1 or 2 glass bottle - **Bottiglie e tubi di ricambio /** Spare bottles and tubing - **Drenaggio toracico tipo Lodi /** Thoracic drainage type Lodi - **Sistema toracentesi e paracentesi /** Thoracentesis paracentesis system **Codice**/ Code: • **M03xxxx(x)(y)(y)** **Possibile aggiunta di max. 3 caratteri alfanumerici al fine di distinguere prodotti tra loro similari. Possibile inserimento di simboli (barre, punti, asterischi, etc) all'interno dei codici** Possible addition of max. 3 alphanumeric digits to distinguish between similar products. Possible insertion of symbols (slash, dot, asterisk, etc.) inside the codes
Modello/i: Model(s):	**Sistemi di drenaggio post-operatorio /** post-operative drainage systems - **Sistema completo con sacca e unità di aspirazione /** Complete system with bag and aspirating unit - **Sistema completo con unità di aspirazione /** Complete system with aspirating unit - **Trocar e cateteri in PVC /** Trocar and PVC catheter **Codice**/ Code: • **M05xxxx(x)(y)(y)** **Possibile aggiunta di max. 3 caratteri alfanumerici al fine di distinguere prodotti tra loro similari** Possible addition of max. 3 alphanumeric digits to distinguish between similar products.

Allegato al Certificato CE n. 1668/MDD - Elenco dei Dispositivi

Annex of EC Certificate no. 1668/MDD - Device List

rev. 0 del/of **2021/03/19**

Categoria di dispositivo: Device category:	**Sistemi di lavaggio** Washing systems
Modello/i: Model(s):	**Set per urologia, artroscopia e laparoscopia /** sets for urology, artroscopy and laparoscopy **Codici**/ Codes: • **MMI/xxx(y)(y)** • **01URxxxx** • **M06xxxx/y** **dove /** where: **MMI = Dispositivo per urologia, artroscopia e laparoscopia /** Set for urology, artroscopy and laparoscopy **x = Caratteri numerici /** Numeric characters **y = Varie tipologie di componentistica /** Different combinations of components **xxxx = Varianti di prodotto /** Product variations **Possibile aggiunta di max. 5 caratteri alfanumerici al fine di distinguere prodotti tra loro similari** Possible addition of max. 5 alphanumeric characters to distinguish between similar products.
Modello/i: Model(s):	**Sistemi di lavaggio intestinale /** intestinal washout sets **Codice /** Code: • **MASxx(y)(y)** **dove /** where: **xx = numero progressivo che indica versioni differenti /** progressive number which indicates different versions **(y)(y) = indica una versione differente /** indicates a different version
Modello/i: Model(s):	**Sistemi di lavaggio urologico /** urology washing systems - **Set di lavaggio per urologia /** Urology washing sets **Codice /** Code: • **M06xxxx/y** **dove /** where: **x = Carattere numerico /** numeric character **y = Carattere alfanumerico /** alphanumeric character **Possibile inserimento di simboli (barra, punto, asterisco, etc) all'interno dei codici** Possible insertion of symbols (slash, dot, asterisk, etc.) inside the code
Modello/i: Model(s):	**Commutatore di fluidi per cateterismo vescicale /** fluids switch for bladder catheterism **Codice /** Code: • **M10001CY**
Marca / Marche: Trademark(s):	**HMC PREMEDICAL**

Categoria di dispositivo: Device category:	**Sonde nasogastriche** Nasogastric tubes

Modello/i: / Model(s):

Sonde NG in POLIURETANO per nutrizione senza pesi e senza guida, trasparenti con riga radiopaca

POLYURETHANE NG feeding Tubes without weights and without guidewire, transparent with radiopaque stripe

Codici / Codes:

- **201xxx(L)**
- **201xxM(L)**

Modello/i: / Model(s):

Sonde NG in POLIURETANO per nutrizione con pesi, trasparenti con riga radiopaca

POLYURETHANE NG feeding Tubes with weights, transparent with radiopaque stripe

Codici / Codes:

- **202xxx(L)**
- **202xxM(L)**

Modello/i: / Model(s):

Sonde NG in POLIURETANO per nutrizione con pesi e guida, radiopache con riga trasparente

POLYURETHANE NG feeding Tubes with weights and with guidewire, radiopaque with transparent stripe

Codici / Codes:

- **205xxxx(L)**
- **205xxxM(L)**

Modello/i: / Model(s):

Sonde NG in POLIURETANO per nutrizione con pesi e guida, radiopache con riga trasparente + cerotto

POLYURETHANE NG feeding Tubes with weights and with guidewire, radiopaque with transparent stripe + plaster

Codice / Code:

- **205xx2M(L)**

Modello/i: / Model(s):

Sonde NG d'aspirazione in POLIURETANO tipo Salem doppio lume

POLYURETHANE NG suction tubes double lumen type Salem

Codici / Codes:

- **250xxx(L)**
- **250xxM(L)**

Modello/i: / Model(s):

Sonde NG in POLIURETANO per nutrizione senza pesi con guida, trasparenti con riga radiopaca

POLYURETHANE NG feeding Tubes without weights and with guidewire, transparent with radiopaque stripe

Codici / Codes:

- **M201xxx(L)**
- **M201xxM(L)**

Modello/i: / Model(s):

Sonde NG in POLIURETANO per nutrizione con pesi e guida, trasparenti con riga radiopaca

POLYURETHANE NG feeding Tubes with weights and with guidewire, transparent with radiopaque stripe

Codici / Codes:

- **M202xxx(L)**
- **M202xxM(L)**

Categoria di dispositivo: **Sonde nasogastriche**
Device category: Nasogastric tubes

Modello/i: **Sonde NG in POLIURETANO per nutrizione radiopache con riga trasparente**
Model(s): POLYURETHANE NG feeding Tubes radiopaque with transparent stripe

Codici / Codes:

- **NGPx/xx(L)**
- **NGPx/xxx(L)**
- **NGPx/xx(L)W**
- **NGPx/xx(L)Y**
- **NGPxx/xx(L)**
- **NGPxx/xxx(L)**
- **NGPxx/xx(L)W**
- **NGPxx/xx(L)Y**

Modello/i: **Sonde NG in POLIURETANO per nutrizione radiopache con riga trasparente**
Model(s): POLYURETHANE NG feeding Tubes radiopaque with transparent stripe

Codici / Codes:

- **NJPx/xxx(L)**
- **NJPxx/xxx(L)**
- **NJPx/xxx(L)W**
- **NJPxx/xxx(L)W**

Modello/i: **Sonde NG in POLIURETANO per nutrizione senza pesi e senza guida, trasparenti con riga radiopaca**
Model(s): POLYURETHANE NG feeding Tubes without weights and without guidewire, transparent with radiopaque stripe

Codici / Codes:

- **RTx/xx(L)**
- **RTxx/xxx(L)**

Modello/i: **Sonde NG d'aspirazione in POLIURETANO doppio lume /**
Model(s): POLYURETHANE NG suction tubes double lumen

Codice / Code:

- **STxx**

Modello/i: **Sonde NG in POLIURETANO per nutrizione trasparenti con riga radiopaca connettori ENFIT**
Model(s): POLYURETHANE NG feeding Tubes transparent with radiopaque stripe ENFIT connectors

Codici / Codes:

- **LGx/xx**
- **LGx/xxx**
- **LGx/xxW**
- **LGxx/xx**
- **LGxx/xxx**
- **LGxx/xxW**

Modello/i: **Sonde NG in POLIURETANO doppio lume connettori ENFIT**
Model(s): POLYURETHANE NG feeding Tubes double lumen with ENFIT connectors

Codici / Codes:

- **EF2L**
- **EF2EL**

Allegato al Certificato CE n. 1668/MDD - Elenco dei Dispositivi

Annex of EC Certificate no. 1668/MDD - Device List

rev. 0 del/of **2021/03/19**

Categoria di dispositivo: Device category:	**Sonde nasogastriche** Nasogastric tubes
Modello/i: Model(s):	**Sonde NG in POLIURETANO doppio lume "Replogle" con connettore ENFIT** POLYURETHANE NG "Replogle" Tubes double lumen with ENFIT connector **Codici /** Codes: • **NF02L** **dove /** where: **xx ; xxx ; xxxx ; xx-xx = Caratteri alfanumerici che identificano diversi CH e lunghezze** / Alphanumeric characters for different CH and lenghts **L = Se aggiunta al codice nella posizione indicata (L), indica versione con connettori ENFIT** / If added to the code in the position (L), it indicates version with ENFIT connectors **Y = Identifica versione della sonda dotata di raccordo ENFit ad Y** / Identifies a version of feeding tube endowed with an ENFit Y connector **W = Identifica versione della sonda dotata di pesi distali** / Identifies a version of feeding tube endowed with distal weights
Marca / Marche: Trademark(s):	**HMC PREMEDICAL**

Allegato al Certificato CE n. 1668/MDD - Elenco dei Dispositivi

Annex of EC Certificate no. 1668/MDD - Device List

rev. 0 del/of **2021/03/19**

Categoria di dispositivo: Device category:	**Surfactant Kit** Surfactant Kit
Modello/i: Model(s):	**Kit per somministrazione surfattante /** surfactant kit **Codice** / Code: • **SFxx** **dove /** where: **XX = Caratteri alfanumerici che identificano varianti di prodotto /** Alphanumeric characters for product versions
Marca / Marche: Trademark(s):	**HMC PREMEDICAL**

Allegato al Certificato CE n. 1668/MDD - Elenco dei Dispositivi

Annex of EC Certificate no. 1668/MDD - Device List

rev. 0 del/of **2021/03/19**

Categoria di dispositivo: Device category:	**Sonde e cannule rettali** Rectal tubes and straws
Modello/i: Model(s):	- **Sonde per lavaggio rettale /** rectal irrigation tubes - **Cannule rettali per infusione /** rectal medicine straw **Codici** / Codes: • **RWxx** • **RCxxx(L)** **dove /** where**:** **XX ; XXX = Caratteri alfanumerici che identificano varianti di prodotto /** Alphanumeric characters for product versions **L = Se aggiunta al codice nella posizione indicata (L), indica versione con connettori ENFIT /** If added to the code in the position (L), it indicates version with ENFIT connectors
Marca / Marche: Trademark(s):	**HMC PREMEDICAL**

Allegato al Certificato CE n. 1668/MDD - Elenco dei Dispositivi

Annex of EC Certificate no. 1668/MDD - Device List

rev. 0 del/of **2021/03/19**

Categoria di dispositivo: Device category:	**Set di produzione, dispensazione, infusione ed accessori** Set for production, dispensation, infusion and accessories
Modello/i: Model(s):	- **Set rampa con valvole e prolunghe /** Manifold set with valves and extension lines - **Set prolunghe per somministrazione /** Extension lines set for administration - **Accessorio reattore /** Reactor **Codici** / Codes: • **aabbbccddd** **dove /** where**:** **aa = campo di due cifre che identificano il tipo di macchina alla quale appartiene il prodotto /** two numbers, identify the machine to which the product belongs; **bbb = campo alfanumerico (lettera, numero, lettera) in grado di identificare la variante della macchina /** letter, number, letter which identify the version of the machine **cc = campo di due cifre per la parte della macchina /** two numbers, identify the part of the machine **ddd: campo di tre cifre progressive di ogni parte della macchina /** three progressive numbers for every part of the machine
Marca / Marche: Trademark(s):	**HMC PREMEDICAL**

Allegato al Certificato CE n. 1668/MDD - Elenco dei Dispositivi

Annex of EC Certificate no. 1668/MDD - Device List

rev. 0 del/of **2021/03/19**

Categoria di dispositivo: Device category:	**Sistemi di aspirazione non attivi** Not active suction systems
Modello/i: Model(s):	- **Tubi medicali di connessione /** Medical connection tubes - Tubi di aspirazione / Suction tubes - **Tubi e cannule di aspirazione per ginecologia /** Cannulas and suction tubes for ginecology - **Cannule di aspirazione /** Suction cannulas - **Cannule di aspirazione con tubi /** Suction cannulas with tubes - **Connettori /** Connectors **Codice** / Code: • **MCI/xxxyyyyy** **dove /** where**:** **MCI = Cannule e Tubi per aspirazione /** Cannulas and aspiration sets **xxx = può assumere i seguenti valori: da 800 a 899 /** can assume the following values: from 800 to 899 **yyyyy = Varie tipologie di componentistica /** Different combinations of components **Possibile aggiunta di max. 8 caratteri alfanumerici al fine di distinguere prodotti tra loro similari** Possible addition of max. 8 alphanumeric characters to distinguish between similar products **Codici** / Codes: • **M01xx(x)(x)(x)(x)(x)(y)(y)(y)** • **M05xxxx** • **M05yyxxxxxx** • **.603xx** • **.81014** **Possibile aggiunta di max. 10 caratteri alfanumerici al fine di distinguere prodotti tra loro similari. Possibile inserimento di simboli (barra, punto, asterisco, etc) all'interno dei codici** Possible addition of max. 10 alphanumeric characters to distinguish between similar products. Possible insertion of symbols (slash, dot, asterisk, etc.) inside the code
Marca / Marche: Trademark(s):	**HMC PREMEDICAL**

CE SERTIFIKATAS

Sertifikato Nr. 1668/MDD

Visos kokybės užtikrinimo sistemos patvirtinimo sertifikatas

Remiantis mūsų atliktu tyrimu pagal direktyvos II priedą, išskyrus 4 skirsnį 93/42/EEB ir jo pataisyta redakcija, patvirtiname, kad:

HMC PREMEDICAL SPA

41037 MIRANDOLA (MO) – VIA BOSCO 1/3 (ITA) – Italija

gamykloje valdo:

41037 MIRANDOLA (MO) – VIA BOSCO 1/3 (ITA) – Italija

41036 MEDOLLA (MO) - VIA GALILEI 6 (ITA) - Italija

kokybės užtikrinimo sistema, užtikrinanti šių gaminių atitiktį:

Procedūrų padėklai pagal užsakymą
Dializės linijos ir priedai
Enteralinės ir parenterinės mitybos sistemos ir priedai
Fotoimunoterapijos rinkinys
Transfuzijos rinkiniai ir priedai
Infuziniai rinkiniai ir priedai – antiblastinio vaisto infuziniai rinkiniai
Krūtinės drenažo ir pooperacinės sistemos
Praplovimo sistemos
Nazogastriniai vamzdeliai
Paviršinio aktyvumo medžiagų rinkinys
Tiesiosios žarnos vamzdeliai ir šiaudeliai
Rinkinys gamybai, paskirstymui, infuzija ir priedai
Neaktyvios atsiurbimo sistemos

serijos ir tipo nuorodas Priede

atitikti atitinkamus esminius pirmiau minėtos direktyvos reikalavimus (nuo projektavimo iki galutinės patikros ir bandymų) ir jam taikoma priežiūra, kaip nurodyta II priedo 5 skirsnyje. III klasės prietaisams tai sertifikatas galioja tik su atitinkamu II.4 priedo CE projekto tyrimo sertifikatu.

Gamintojo parašas//

Data: ***2014-04-22***
Atnaujinimas: ***2021-05-07***
Pakeitimo data: ***2021-03-19***
Galiojimo data: ***2024-04-18***

Pažyma Nr. 1668/MDD

CE SERTIFIKATAS

Viso kokybės užtikrinimo sistemos patvirtinimo sertifikatas

Nuoroda į IMQ failų numerius:

10AO00044; DM15A0517007-01; DM15E0572595-01; DM16A0606701-01; DM16E0628711-01; DM16-0000514; DM16-0006993-01; DM-16-0011324-01; DM17-0009716-01; DM17-0018804-01; DM18-0024318-01; DM18-0031312-01; DM19-0034618-01; DM19-0043096-01; DM20-0049475-01; DM20-0057076-01; DM21-0065367-01.

Šį patvirtinimo sertifikatą išdavė IMQ S.p.A., kaip paskelbtoji įstaiga pagal Direktyvą 93/42/EEB ir jos pataisyta versija. Notifikuotoji įstaiga, paskelbta Europos Komisijai numeriu: 0051.

Data:	***2014-04-22***	***Gamintojo parašas//***
Atnaujinimas:	***2021-05-07***	
Pakeitimo data:	***2021-03-19***	
Galiojimo data:	***2024-04-18***	

CE SERTIFIKATAS

Sertifikato Nr. 1668/MMD

Priedas

Procedūrų padėklai pagal užsakymą
Dializės linijos ir priedai
Enteralinės ir parenterinės mitybos sistemos ir priedai
Fotoimunoterapijos rinkinys
Transfuzijos rinkiniai ir priedai
Infuziniai rinkiniai ir priedai – antiblastinio vaisto infuziniai rinkiniai
Krūtinės drenažo ir pooperacinės sistemos
Praplovimo sistemos
Nazogastriniai vamzdeliai
Paviršinio aktyvumo medžiagų rinkinys
Tiesiosios žarnos vamzdeliai ir šiaudeliai
Rinkinys gamybai, paskirstymui, infuzija ir priedai
Neaktyvios atsiurbimo sistemos

Tipo ref. kaip dokumentas „EB sertifikato Nr. 1668/MDD priedas – įrenginių sąrašas“ red. 0 data 2021-03-19; šis priedas yra neatskiriama ir esminė šio sertifikato dalis**.**

Data:	***2014-04-22***	***Gamintojo parašas//***
Atnaujinimas:	***2021-05-07***	
Pakeitimo data:	***2021-03-19***	
Galiojimo data:	***2024-04-18***	

Prietaiso kategorija: Krūtinės drenažo ir pooperacinės sistemos

Modelis (-iai): toracentezės ir paracentezės rinkiniai

Kodai:

- **MCI/xxxTOR**
- **MCI/xxxPAR**

kur:
MCI = Thoracentesis ir paracentesis rinkiniai
xxx = Įvairūs komponentų deriniai
TOR = toracentezės rinkinys
PAR = paracentezės rinkinys

Galimas papildomas maks. 1 raidinis ir skaitmeninis skaitmuo, leidžiantis atskirti panašius produktus

Modelis (-iai): krūtinės drenažo Sistema

- Krūtinės drenažo sistemos 1,2 arba 3 plastikiniai buteliai
- Krūtinės ląstos drenažas sistemos 1 arba 2 stikliniai buteliai
- Atsarginiai buteliai ir vamzdeliai
- Krūtinės ląstos drenažo tipas Lodi
- Toracentezės paracentezės sistema

Kodas:

- **M03xxxx(x)(y)(y)**

Galimas papildomas maks. 3 raidiniai ir skaitmeniniai skaitmenys, skirti atskirti panašius produktus. Galima simbolių (pasvirojo brūkšnio, taško, žvaigždutės ir kt.) įterpimas į kodus

Modelis (-iai): pooperacinės drenažo sistemos

- Pilna sistema su maišelis ir įsiurbimo blokas
- Pilna sistema su įsiurbimo bloku
- Trocar ir PVC kateteris

Kodas:

- **M05xxxx(x)(y)(y)**

Galimas papildomas maks. 3 raidiniai ir skaitmeniniai skaitmenys, skirti atskirti panašius produktus.

Business Stream Products
Certification Department

TÜVRheinland®
LGA
Precisely Right.

TÜV Rheinland LGA Products GmbH • 51105 Köln

Jiangsu BANA Medical Technology Co., Ltd.
No.28-3, Guihua Road, Zhonglou Economic Development Zone,
Changzhou,
213013 Jiangsu
P.R. China

Contact

Tel. +49 911 655-5225
Mail: medical-products@de.tuv.com

Date May 22, 2024

Notified Body Confirmation Letter
Reference. : 326008266

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This letter confirms that **TÜV Rheinland LGA Products GmbH**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **0197** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Jiangsu BANA Medical Technology Co., Ltd.
No.28-3, Guihua Road, Zhonglou Economic Development Zone,
Changzhou, 213013 Jiangsu
P.R. China
SRN Number: CN-MF-000025963

The devices covered by the formal application and the written agreement mentioned above are identified in the tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by March 20, 2023 for the relevant devices.

TÜV Rheinland
LGA Products GmbH

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Phone. +49 911 655 5225
Fax +49 911 655 5226
service@de.tuv.com
www.tuv.com/safety

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- May 26, 2026 for Class III custom-made implantable devices
- December 31, 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- December 31, 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- December 31, 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body

Herbert Zhong
2024.05.22
'00'08+ 10:08:53

Herbert Zhong
Certification body

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	**MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)**	**If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device**	**MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification**
Disposable Clip Appliers Models:TQ5、TQ10-J Basic UDI-DI: 69411733TQJ3U	Class IIb excluding Class IIb implantable non-WET	Disposable Clip Appliers Models: TQ5、TQ10	Certificate #: HD 60142092 0001 NB #: 0197
Disposable Clip Appliers Models:TQ10 Basic UDI-DI: 69411733TQS4E	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate #: HD 60142092 0001 NB #: 0197
Disposable Endoscopic Retrieval Bags Models:QW1 Basic UDI-DI: 69411733QW12F	Class IIa	N/A	Certificate #: HD 60142092 0001 NB #: 0197

Device name or Basic UDI-DI (under MDR application)	**MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)**	**If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device**	**MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification**
Disposable Endoscopic Retrieval Bags Models:QW2 Basic UDI-DI: 69411733QW22H	Class IIa	N/A	Certificate #: HD 60142092 0001 NB #: 0197
Disposable Endoscopic Retrieval Bags Models:QW4 Basic UDI-DI: 69411733QW42M	Class IIa	N/A	Certificate #: HD 60142092 0001 NB #: 0197
Disposable Endoscopic Retrieval Bags Models:QW5 Basic UDI-DI: 69411733QW52P	Class IIa	N/A	Certificate #: HD 60142092 0001 NB #: 0197
Disposable Endoscopic Retrieval Bags Models:QW7 Basic UDI-DI: 69411733QW72T	Class IIa	N/A	Certificate #: HD 60142092 0001 NB #: 0197
Disposable Endoscopic Retrieval Bags Models:QW8 Basic UDI-DI: 69411733QW82V	Class IIa	N/A	Certificate #: HD 60142092 0001 NB #: 0197

Device name or Basic UDI-DI (under MDR application)	**MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)**	**If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device**	**MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification**
Disposable Suction and Irrigation Tubes Models: CX330-II, CX430-II Basic UDI-DI: 69411733CXIISP	Class IIa	Disposable Suction and Irrigation Tubes Models: CX330, CX430	Certificate #: HD 60142092 0001 NB #: 0197
Disposable Suction and Irrigation Tubes Models: CX330-III, CX430-III Basic UDI-DI: 69411733CXIIIPV	Class IIa	Disposable Suction and Irrigation Tubes Models: CX330, CX430	Certificate #: HD 60142092 0001 NB #: 0197
Hernia Staplers Models: LW-350, LW-110 Basic UDI-DI: 69411733LWEA	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate #: HD 60142092 0001 NB #: 0197
Dilators Models: 5,7,9,11,13,15 Basic UDI-DI: 69411733KZED	Class I devices placed on the market in sterile condition	N/A	Certificate #: HD 60142092 0001 NB #: 0197
Disposable Trocars Models: CCQ-W Basic UDI-DI: 69411733CCQWR2	Class IIa	N/A	Certificate #: HD 60142092 0001 NB #: 0197
Disposable Trocars Models: CCQ-Y Basic UDI-DI: 69411733CCQYR6	Class IIa	N/A	Certificate #: HD 60142092 0001 NB #: 0197

Device name or Basic UDI-DI (under MDR application)	**MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)**	**If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device**	**MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification**
Disposable Trocars Models: CCQ-G Basic UDI-DI: 69411733CCQGQ2	Class IIa	Disposable Trocars Models: CCQ-W	Certificate #: HD 60142092 0001 NB #: 0197
Disposable Veress Needles Models: QF-120, QF-150 Basic UDI-DI: 69411733QFDP	Class IIa	N/A	Certificate #: HD 60142092 0001 NB #: 0197
Disposable Endoscopic Ligating Loops Models:TZ-300 Basic UDI-DI: 69411733TZF8	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate #: HD 60142092 0001 NB #: 0197
Hernia Patches Models: SB-A Basic UDI-DI: 69411733SBAZM	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate #: HD 60142092 0001 NB #: 0197
Hernia Patches Models: SB-B Basic UDI-DI: 69411733SBBZP	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate #: HD 60142092 0001 NB #: 0197
Hernia Patches Models: SB-C Basic UDI-DI: 69411733SBCZR	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate #: HD 60142092 0001 NB #: 0197
Disposable Prepuce Cutter Staplers Models: NBWA Basic UDI-DI: 69411733NBWASG	Class IIa	N/A	Certificate #: HD 60142092 0001 NB #: 0197

Device name or Basic UDI-DI (under MDR application)	**MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)**	**If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device**	**MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification**
Disposable Prepuce Cutter Staplers Models: NBWB Basic UDI-DI: 69411733NBWBSJ	Class IIa	N/A	Certificate #: HD 60142092 0001 NB #: 0197
Disposable Prepuce Cutter Staplers Models: NBWC Basic UDI-DI: 69411733NBWCSL	Class IIa	N/A	Certificate #: HD 60142092 0001 NB #: 0197
Disposable Endoscopic Graspers Models: ZQ330、ZQ430 Basic UDI-DI: 69411733ZQF8	Class IIa	N/A	Certificate #: HD 60142092 0001 NB #: 0197
Disposable Endoscopic Scissors Models: JD330、JD430 Basic UDI-DI: 69411733JDCW	Class IIa	N/A	Certificate #: HD 60142092 0001 NB #: 0197
Disposable Endoscopic Dissectors Models: FQ330、FQ430 Basic UDI-DI: 69411733FQDC	Class IIa	N/A	Certificate #: HD 60142092 0001 NB #: 0197
Biopsy Forceps Models: HQ1.8、HQ2.3 Basic UDI-DI: 69411733HQDJ	Class IIa	N/A	Certificate #: HD 60142092 0001 NB #: 0197

Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
None			

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024-5-22	326008266	Initial issue

Sertifikavimo Deaprtamentas

TÜV Rheinland LGA Products GmbH • 51105 Köln
Jiangsu BANA Medical Technology Co., Ltd.
No.28-3, Guihua Road, Zhonglou Economic Development Zone,
Changzhou,
213013 Jiangsu
P.R. China

Contact
Tel. +49 911 655-5225
Mail: medical
products@de.tuv.com
Date May 22, 2024

Notifikuotosios Įstaigos Patvirtinimo Laiškas
Nuoroda: 326008266

Tiems, kam tai gali būti aktualu

Oficialaus prašymo statuso patvirtinimas, rašytinis susitarimas ir tinkamą priežiūrą pagal Reglamentą ES 2023/607 iš dalies keičiantys reglamentus (ES) 2017/745 ir (ES) 2017/746 dėl pereinamojo laikotarpio nuostatos tam tikriems medicinos prietaisams ir in vitro diagnostikai Medicininiai prietaisai.

Šis laiškas patvirtina, kad notifikuotoji įstaiga **TÜV Rheinland LGA Products GmbH** (NB), priskirtas pagal Reglamentą (ES) 2017/745 (MDR) ir nurodytas pagal **0197** NANDO, gavo oficialų prašymą pagal MDR VII priedo 4.3 skirsnio pirmą pastraipą ir pasirašė rašytinį dokumentą susitarimą pagal VII priedo 4.3 skirsnio antrąją pastraipą MDR su šiuo gamintoju:

Jiangsu BANA Medical Technology Co., Ltd.
Nr.28-3, Guihua Road, Zhonglou ekonominės plėtros zona,
Changzhou, 213013 Jiangsu
P.R. Kinija
SRN numeris: CN-MF-000025963

Įrenginiai, kuriems pateikta oficiali paraiška ir nurodytas rašytinis susitarimas nurodyti toliau pateiktose lentelėse. 1 lentelėje nurodyti įrenginiai, kuriems gautas MDR prašymas, sudaryta rašytinė sutartis ir dėl kurios NB taip pat yra atsakinga už tinkamą priežiūrą pagal taikomą direktyvą. 2 lentelėje nurodyti įrenginiai, kuriems buvo gauta MDR programa ir sudaryta rašytinė sutartis, tačiau NB atsakomybės dar neprisiėmė tinkamai prižiūrėti atitinkamus įrenginius pagal taikomus reikalavimus direktyvą.

Prietaisams, kuriems išduoti sertifikatai pagal Direktyvą 90/385/EEB (AIMDD) arba Direktyva 93/42/EEB (MDD), kuri nustojo galioti po 2021 m. gegužės 26 d., bet anksčiau 2023

m. kovo 20 d. nebuvo atšaukta, šis raštas taip pat patvirtina, kad gamintojas arba pasirašė rašytinį susitarimą pagal MDR iki datos MDD/AIMDD (sertifikato galiojimo laikas); arba pateikė įrodymų, kad kompetentinga institucija valstybė narė buvo suteikusi leidžiančią nukrypti nuostatą arba atleisti nuo taikytinos atitikties vertinimo procedūros pagal MDR 59 straipsnio 1 dalį arba 97 straipsnio 1 dalį MDR atitinkamai iki 2023 m. kovo 20 d. atitinkamiems įrenginiams.
Pereinamojo laikotarpio terminai, taikomi įrenginiams, kuriems taikomas šis raštas, atsižvelgiant į tai, kad gamintojas nuolat laikosi kitų straipsnyje nurodytų sąlygų MDR 120.3c (su pakeitimais, padarytais (ES) 2023/607), pateikiami toliau:
• 2026 m. gegužės 26 d. III klasės pagal užsakymą gaminamiems implantuojamiems prietaisams
• 2027 m. gruodžio 31 d. III klasės prietaisams ir IIb klasės implantuojamiems prietaisams. Išskyrus nusistovėjusias technologijas (WET - siūlai, kabės, odontologijos plombos, dantų breketai, dantų vainikėliai, varžtai, pleištai, plokštelės, laidai, kaiščiai, spaustukai ir jungtys)
• 2028 m. gruodžio 31 d. kitiems IIb klasės, IIa klasės, I klasės įrenginiams pateikiami į rinką sterilūs arba turintys matavimo funkciją
• 2028 m. gruodžio 31 d. įrenginiams, kuriems netaikomi MDD reikalavimai, bet reikalingi pagal MDR (pvz., I klasės įrenginiai, kurie kvalifikuojami kaip pakartotinai naudojami chirurginiai instrumentai)

Notifikuotosios Įstaigos
Už Sertifikavimą atsakingas asmuo
Herbert Zhong

parašas

EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60142092 0001

Report No.: 15095988 008

Manufacturer:
Jiangsu BANA Medical Technology
Co., Ltd.
No. 28-3 Guihua Road
Zhonglou Economic Development Zone
Changzhou
213013 Jiangsu
P.R. China

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: HD 60138384 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Notified Body

Effective Date: 2020-11-21

Date: 2020-11-21

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜVRheinland®

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60142092 0001
Report No.: 15095988 008

Manufacturer:
Jiangsu BANA Medical Technology Co., Ltd.
No. 28-3 Guihua Road
Zhonglou Economic Development Zone
Changzhou
213013 Jiangsu
P.R. China

Products:

- Hernia Patches
- Disposable Prepuce Cutter Staplers
- Hernia Staplers
- Disposable Endoscopic Ligating Loops
- Disposable Endoscopic Graspers
- Disposable Endoscopic Scissors
- Disposable Endoscopic Dissectors
- Disposable Suction and Irrigation Tubes
- Biopsy Forceps
- Disposable Endoscopic Retrieval Bags
- Disposable Trocars
- Disposable Clip Appliers
- Disposable Veress Needles
- Non-sterile Metallic Bone Plates
- Non-sterile Metallic Bone Screws
- Spinal Internal Fixation
- Non-sterile Metallic Intramedullary Femur Nails
- Non-sterile Metallic Intramedullary Tibia Nails
- Non-sterile Metallic Intramedullary Humerus Nails

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Date: 2020-11-21

Fuxiu Sheng

TÜVRheinland®

Doc. 2/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60142092 0001
Report No.: 15095988 008

Manufacturer:
Jiangsu BANA Medical Technology Co., Ltd.
No. 28-3 Guihua Road
Zhonglou Economic Development Zone
Changzhou
213013 Jiangsu
P.R. China

Aspects of manufacture concerned with securing and maintaining sterile conditions:

- Dilators

Notified Body

TÜV Rheinland LGA Products GmbH Prüfstelle III

Date: 2020-11-21

Ruxiu Sheng

EC Sertifikatas

Direktyvos 93/42/EEC Priedas Nr. II, išskyrus 4 skirsnį

KOKYBĖS UŽTIKRINIMO SISTEMA

Medicinos prietaisai

Registracijos Nr.: HD 60142092 0001

Ataskaitos Nr.: 15095988 008

Gamintojas: Jiangsu BANA Medical Technology CO., LTD.
No. 28-3 Guihua Road
Zhonglou Economic Development Zone
Changzhou
213013 Jiangsu
P.R. Kinija

Produktai: Medicinos prietaisai (žiūrėti pridėtame produktų priede)

Galioja iki: 2024-05-26

Notifikuojančioji įstaiga patvirtina, kad toliau išvardinti produktai atitinka direktyvos 93/42/EEC II Priedą, išskyrus 5 skirsnį. Aukščiau minimas gamintojas įtvirtino ir vykdo kokybės užtikrinimo sistemą, taip pat periodinę priežiūrą, patvirtintą minimos direktyvos II Priedo 5 skirsnyje. Pateikimas į rinką produktų, kuriems taikomas šis sertifikatas ir EB pakuotės dizaino atitikimo sertifikatas pagal II Priedo 4 skirsnį, yra galimas.

Įsigaliojimo Data: 2020-11-21

Data: 2020-11-21

Notified Body

Ruxiu Sheng

TUV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Priedas prie Sertifikato

Registracijos Nr.: HD 60142092 0001

Ataskaitos Nr.: 15095988 008

Gamintojas: Jiangsu BANA Medical Technology
CO., LTD.
No. 28-3 Guihua Road
Zhonglou Economic Development Zone
Changzhou
213013 Jiangsu
P.R. Kinija

Produktai:

- Išvaržos Tinklai;
- Vienkartiniai Stapleriai;
- Išvaržų Stapleriai;
- Vienkartinės Endoskopinės Ligavimo Kilpos;
- Vienkartiniai Endoskopiniai Žnyplės;
- Vienkartinės Endoskopinės Žirklės;
- Vienkartiniai Endoskopiniai Disektoriai;
- Vienkartiniai Siurbimo / Irigavimo Vamzdeliai;
- Biopsinės Žnyplės;
- Vienkartiniai Endoskopiniai Organų/Audinių Ištraukimo Maišeliai;
- Vienkartiniai Trokarai;
- Vienkartiniai Kabučių Aplikatoriai;
- Vienkartinės Veress Adatos;
- Nesterilūs Metaliniai Kaulų Implantai;
- Nesterilūs Metaliniai Kaulų Sraigtai;
- Vidiniai Stuburo Fiksatoriai;
- Nesterilios Metalinės Intramedulinės Šlaunikaulio Vinys;
- Nesterilios Metalinės Intramedulinės Blauzdikaulio Vinys;
- Nesterilios Metalinės Intramedulinės Žąstikaulio Vinys.

Data: 2020-11-21

Fuxiu Sheng

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Priedas prie Sertifikato

Registracijos Nr.: HD 60142092 0001

Ataskaitos Nr.: 15095988 008

Gamintojas: Jiangsu BANA Medical Technology
CO., LTD.
No. 28-3 Guihua Road
Zhonglou Economic Development Zone
Changzhou
213013 Jiangsu
P.R. Kinija

Gamybos aspektai, susiję su sterilių sąlygų užtikrinimu ir palaikymu:

- Dilatoriai.

Notified Body

Fuxiu Sheng

Date: 2020-11-21

Organismo Notificato 0373
Notified Body 0373

Istituto Superiore di Sanità

Certificato n° *Certificate no.* **QCT-0164-21**

Addendum n° *addendum no.* **01-21**

Data prima emissione *First issue date*	**02.03.2021**
Data di emissione corrente *Current issue date*	**02.03.2021**
Data di scadenza *Expiry date*	**26.05.2024**

DICHIARAZIONE CE DI CONFORMITA' SISTEMA COMPLETO DI GARANZIA DI QUALITA'

secondo l'Allegato II escluso (4) della Direttiva Europea 93/42/CEE e successive modifiche ed integrazioni.
(recepita in Italia con il D.Lgs. n. 46 del 24.02.1997 e successive modifiche ed integrazioni)

EC DECLARATION OF CONFORMITY FULL QUALITY ASSURANCE SYSTEM

according to Annex II excluding (4) of EC Directive 93/42/EEC and subsequent modifications and integrations.
(transposed in Italy by the D.Lgs. n. 46 issued on 24.02.1997 and subsequent modifications and integrations)

L'Istituto Superiore di Sanità, Organismo Notificato 0373, certifica che il sistema completo di garanzia della qualità attuato da

The Istituto Superiore di Sanità, Notified Body 0373, certifies that the total quality assurance system enforced by

KNOW MEDICAL S.r.l.

Sede Legale/ *Registered Office****: Via Giuseppe Verdi, 15 – 46019 Viadana (MN) Italia***

Altre sedi del Fabbricante /Other sites of the Manufacturer:

Sede Operativa/ *Operative Office****: Via Guido Rossa, 36 Zona Industriale Gerbolina – 46019 Viadana (MN) Italia***

per il dispositivo/i *for the device(s)*

(vedi allegato tecnico/ see technical sheet)*

è conforme ai requisiti applicabili della Direttiva Europea 93/42/CEE e successive modifiche ed integrazioni.

is in compliance with the applicable requirements of Council Directive 93/42/EEC and subsequent modifications and integrations.

Il Direttore dell'Organismo Notificato
The Director of Notified Body
(Dott.ssa Roberta Marcoaldi)

MARCOALDI ROBERTA
02.03.2021 10:49:40
UTC

*** L'allegato tecnico è parte integrante del presente Certificato**
The technical sheet is an integral part of this Certificate.

Organismo Notificato 0373
Notified Body 0373

Istituto Superiore di Sanità

ALLEGATO TECNICO

TECHNICAL SHEET

Il Certificato n°
The Certificate no. **QCT-0164-21**

Addendum n°
addendum no. **01-21**

di cui il presente allegato tecnico è parte integrante, è da considerarsi riferito solo al/ai seguente/i prodotto/i soggetto/i a sorveglianza:

of which this technical sheet is an integral part, refers only to the following product(s) that are subject to surveillance:

***Classe IIa** (Class IIa)*

Nome prodotto *(Product name)*	***Codice*** *(Code)*
Dispositivi per infusione trasfusione ed accessori, sterili (deflussori, trasfusori, burette, prolunghe, connettori vari) *Infusion and transfusion set and accessories (infusion set, transfusion set, burette, extension lines, connectors)*	*IS XXXXYY O*[1] *TS XXXXYY O*[2] *BG XXXX YY O*[3] *FL1 XXX O*[4] *EL XXXX YY O*[5]

I codici di cui sopra hanno il seguente significato, come da criteri di codifica presentati dalla Ditta e conservati presso questo Organismo Notificato:
1IS: Infusion Set; XXXX: numeri che indicano le caratteristiche del prodotto; YY: numeri (da 01 a 99) che indicano le possibili varianti;
2TS: Transfusion Set; XXXX: numeri che indicano le caratteristiche del prodotto; YY: numeri (da 01 a 99) che indicano le possibili varianti; O: lettera che indica la sterilizzazione ad Ossido di Etilene.
3BG: Burette Graduated; XXXX: numeri che indicano la capacità della buretta e la presenza o non del microgoccia; YY: numeri (da 01 a 99) che indicano le possibili varianti; O: lettera che indica la sterilizzazione ad Ossido di Etilene.
4 FL1: Flow Regulator; XXX: numeri che indicano le caratteristiche/varianti del regolatore di flusso; O: lettera che indica la sterilizzazione ad Ossido di Etilene.
5 EL:Extension Line; XXXX: numeri che indicano le caratteristiche del prodotto; YY: numeri (da 01 a 99) che indicano le possibili varianti; O: lettera che indica la sterilizzazione ad Ossido di Etilene.

Valutazione della conformità: vedi MOD-341-01-01 n° 157/21
Conformity assessment: MOD-341-01-01 n. 157/21

Il Direttore dell'Organismo Notificato
The Director of Notified Body
(Dott.ssa Roberta Marcoaldi)
MARCOALDI ROBERTA
02.03.2021 10:50:26
UTC

KNOW MEDICAL S.r.l.

Object: Conformity Declaration of disposable device's range *"MEDICAL DEVICES FOR INFUSION, TRANSFUSION AND ACCESSORIES"*, manufactured by Know Medical S.r.l., according to standard rule of Annex I of EC Directive 93/42/EEC, modified with EC Directive 2007/47/EC, according to Annex II.

Herewith, Know Medical S.r.l., located Registered Office in Via Giuseppe Verdi 15 46019 Viadana (MN) and Operative Office in Via Guido Rossa 36 Zona Industriale Gerbolina 46019 Viadana (MN), represented by General Manager Marco Minghetti, as manufacturer of disposable device's range "**DISPOSABLE MEDICAL DEVICES FOR INFUSION AND TRANSFUSION SET AND ACCESSORIES"**, identified by code BURETTE BGxxxxyy-O, INFUSET ISxxxxyy-O, TRANSFUSET TSxxxxyy-O, EXTENSION LINE ELxxxxyy-O, DOSIKNOW FL1 xxx O declares that:

"product described in Technical File "DISPOSABLE MEDICAL DEVICES FOR INFUSION AND TRANSFUSION SET AND ACCESSORIES", satisfy every rule according to Annex I of EC Directive 93/42/EEC, transposed in Italy by D. Lgs. N° 46 dated 1997, and following modifications (ref.: EC Directive 2007/47/EC)"

Know Medical S.r.l. declares and guarantees under its own responsibility as follow:

1. the device's range mentioned above, satisfies the standard rules according to Annex I of EC Directive 93/42/EEC, modified with EC Directive 2007/47/EC;
2. the device's range mentioned above, it belongs to Class IIa, rule 2 and 7 of Annex IX EC Directive 93/42/EEC, modified with EC Directive 2007/47/EC;
3. devices mentioned above are sold in sterile packaging;
4. manufacturer engaged itself to preserve and to keep available to Notified Body all documentation regarding this disposable device's range (technical file and production registration) for a period of at least 10 years starting from last manufacturing date;
5. following to the put on the market of this disposable's range, manufacturer has notified to Authority, the application procedures of post-selling products' surveillance as requested by EC Directive 93/42/EEC, modified by EC Directive 2007/47/EC;
6. CE Certification Nr. QCT 0164-21-0121 issued on 02.03.2021 by "Istituto Superiore di Sanità nr.0373" will be valid until **26/05/2024**;
7. the devices mentioned above are not measuring instruments;
8. the devices mentioned above are not destined to clinical inquiries;
9. the devices range is manufactured according to the Quality System approved by "Istituto Superiore di Sanità";
10. the sterilization process is done using Ethylene Oxide at Steril Verona S.r.l. located in Erbè (VR) via San Giuseppe 31 trough validate procedures.

Viadana (MN), 02/03/2021

hetti
erale)

KNOW MEDICAL Società Commerciale Internazionale Import-Export S.r.l.
Sede legale: Via Giuseppe Verdi, 15 – 46019 Viadana (MN) Italia
Sede amministrativa e stabilimento produttivo: Via Guido Rossa, 36 – Zona Industriale Gerbolina - 46019 Viadana (MN)
Tel. +39 0375 781774 - Fax +39 0375 785933 - E-mail: info@knowmedical.com - Web: www.knowmedical.com
C.F./P. IVA 01576010209 - Iscrizione al R.E.A. di Mantova Nr. 167664 il 04/04/1990
Capitale Sociale € 10.400,00 int. vers. - Iscrizione al R.I./C.C.I.A.A. di Mantova Nr. MN030-14698 il 19/02/1996

/KNOW MEDICAL S.r.l./

<u>Tikslas:</u> Vienkartinių prietaisų prekių grupės Atitikties Deklaracija „MEDICINOS PRIETAISAI INFUZIJAI, TRANSFUZIJAI IR PRIEDAI“, pagaminta Know Medical S.r.l., pagal CE Direktyvos 93/42/EEC, modifikuotos CE Direktyva 2007/47/EC pagal VII priedą, I priedo strandarto taisyklę,

Čia, Know Medical S.r.l., kurios vietinis Registruotas ofisas yra Via Giuseppe Verdi 15 46019 Viadana (MN) ir Operatyvinis ofisas yra Via Guido Rossa 36 Zona Industriale Gerbolina 46019 Viadana (MN), atstovaujama generalinio direktoriaus Marco Minghetti, vienkartinių prietaisų prekių grupės gamintoja „**VIENKARTINIAI MEDICINOS PRIETAISAI INFUZIJAI, TRANSFUZIJAI IR PRIEDAI“**, indentifikuojami kodais BURETTE Bgxxxxyy-O, INFUSET ISxxxxyy-O, TRANSFUT TSxxxxyy-O, EXTENSION LINE and TP-INTER Elxxxxyy-O, DOSIKNOW FL1 xxx O patvirtina, kad:

„produktas apibūdintas Techniniame Faile „VIENKARTINIAI MEDICINOS PRIETAISAI INFUZIJAI, TRANSFUZIJAI IR PRIEDAI“ patenkina kiekvieną taisyklę pagal EB Direktyvos 93/42/EEB I priedą, perkeltą į nacionalinę teisę Italijoje D. Lgs. N^{o} 46 1997 metais, ir toliau einančias modifikacijas (ref. EB Direktyva 2007/47/EB)“

Know Medical S.r.l. Patvirtina ir užtikrina su savo atsakomybe:

1. Prietaisų grupė paminėta aukščiau atitinka standartines taisykles pagal EB Direktyvos 93/42/EEC, modifikuotos EB Direktyva 2007/47/EB, I priedą.
2. Prietaisų grupė paminėta aukščiau, priklauso IIa Klasei, pagal EB Direktyvos 93/42/EEB IX Priedo 2 ir 7 taisykles
3. Prietaisai minėti aukščiau yra parduodami steriliame įpakavime.
4. Gamintojas įsipareigojo saugoti ir pateikti notifikuotajai įstaigai visą dokumentaciją, susijusią su šia vienkartinių prietaisų prekių grupe (techninis failas ir gamyba), ne trumpiau kaip 10 metus nuo paskutinės gamybos datos;
5. Pateikus į rinką šią vienkartinių prietaisų prekių grupę, gamintojas pranešė Institucijai, paraiškų procedūros, kaip reikalaujama pagal EB direktyvą 93/42 / EEB, iš dalies pakeistą EB direktyva 2007/47 / EB;
6. CE sertifikatas, išduotas „Istituto Superiore di Sanita“, galios iki 26/05/2024;
7. Aukščiau minėti prietaisai nėra matavimo instrumentai.
8. Aukščiau minėti prietaisai nėra skirti klinikiniams tyrimams
9. Prietaisų grupė yra gaminama pagal Kokybės Sistemą patvirtintą „Istituto Superiore si Sanita“
10. Sterilizacijos procesas yra vykdomas naudojant Etileno Oksidą, Steril Verona S.r.l. Esančioje Erbe (VR) via San Giuseppe 31 pagal patvirtintas procedūras.

Viadana (MN), 02/03/2021

Marco Minghetti
(Generalinis Direktorius)
/parašas/
/antspaudas/

DNV·GL

EC CERTIFICATE

Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
10016-2017-CE-RGC-NA-PS Rev. 1.0	PRJC-523132-2015-PRC-CHN	26 May 2024

This is to certify that the quality system of:

Koo (Shanghai) Industries Co., Ltd.

100 Zhongde Road, Xiaokunshan Town, Songjiang, Shanghai 201614, P.R. China

For design, production and final product inspection/testing of:

STERILE AND NON-STERILE MEDICAL DEVICES FOR ANESTHESIA, RESPIRATORY AND CRITICAL CARE

Has been assessed with respect to:

THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN ANNEX II EXCLUDING SECTION 4 OF COUNCIL DIRECTIVE 93/42/EEC ON MEDICAL DEVICES, AS AMENDED

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 7 July 2020

NORWEGIAN ACCREDITATION

PROD 021

For:
DNV GL PRESAFE AS

Notified Body No.: 2460

Eugenie Winger Husebye

The certificate is digitally verified by blockchain technology. For more info, see www.dnvgl.com/assurance/certificates-in-the-blockchain.html

Certificate No.:
10016-2017-CE-RGC-NA-PS Rev. 1.0

Project No.:
PRJC-523132-2015-PRC-CHN

Valid Until:
26 May 2024

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	**Description**	**Issue Date**
0.0	Original Certificate	2017-05-31
1.0	**Recertification**	**2020-07-07**

Products covered by this Certificate:

Product Description	**Product Name**	**Class**
Sterile Medical Devices for Anesthesia, Respiratory and Critical Care	Laryngeal Mask Airway, including: Crystal Airway Mask:KM-817, KM-827, KM-837, KM-847, KM-857, KM-867, KM-877, Crystal Airway Mask-Contour: KM-816, KM-826, KM-836, KM-846, KM-856, KM-866, KM-876, KM-886 Crystal Airway Mask-Contour Plus: KM-815, KM-825, KM-835, KM-845, KM-855, KM-865, KM-875, KM-885 Flexible Crystal Airway Mask (Flex CAM): KM-818, KM-828, KM-838, KM-848, KM-858	IIa
Non-sterile Medical Devices for Anesthesia, Respiratory and Critical Care	Anesthesia Face Mask: KM-200, KM-201, KM-202, KM-203, KM-204, KM-205, KM-206, KM-207, KM-208, KM-209, KM-200S, KM-201S, KM-202S, KM-203S, KM-204S, KM-205S, KM-206S, KM-207S, KM-360, KM-361, KM-362, KM-363, KM-364, KM-365, KM-366, KM-367, KM-273, KM-274, KM-275, KM-2731, KM-2741, KM-2751, KM-273A, KM-274A, KM-275A, KM-276, KM-276L, KM-277, KM-278, KM-279, KM-280, KM-2761, KM-2761L, KM-2771, KM-2781, KM-2791, KM-2801, KM-276A, KM-276AL, KM-277A, KM-278A, KM-279A, KM-280A, KM-200P, KM-201P, KM-202P, KM-203P, KM-204P, KM-205P, KM-206P, KM-207P, KM-411, KM-412, KM-413, KM-421, KM-422, KM-423, KM-320, KM-320H, KM-321, KM-321H, KM-322, KM-322H, KM-323, KM-323H, KM-324, KM-324H, KM-325, KM-326, KM-327, KM-400G1, KM-401G1, KM-402G1, KM-403G1, KM-404G1, KM-405G1, KM-406G1, KM-407G1	IIa

	Oxygen Masks: KM-210, KM-211, KM-214, KM-240, KM-241, KM-242, KM-243, KM-212, KM-213, KM-2141, KM-244, KM-250, KM-251, KM-236, KM-300, KM-302, KM-261, KM-261A, KM-263, KM-263A, KM-260, KM-270, KM-262, KM-272, KM-284, KM-286, KM-285, KM-287, KM-260A, KM-908, KM-918, KM-282, KM-283, KM-220, KM-221	IIa
	Breathing Exercisers: KM-802, KM-805, KM-805C, KM-8051, KM-803, KM-8031, KM-803HCN, KM-803HCP, KM-803HCA, KM-803HCL, KM-803HC, KM-804, KM-803K, KM-803D, KM-803W, KM-803Y, KM-803B, KM-803G, KM-803O, KM-803M, KM-803C, KM-803P, KM-8032, KM-8040, KM-8041, KM-8042, KM-8043	IIa
	Nasal Oxygen Cannula: KM-218, KM-215, KM-222, KM-224, KM-226, KM-217, KM-219, KM-216, KM-223, KM-225, KM-227, KM-228, KM-230, KM-232, KM-234, KM-229, KM-231, KM-233, KM-235, KM-228A, KM-290, KM-292, KM-291, KM-293, KM-2101, KM-2109, KM-2111, KM-2106, KM-2102, KM-2103, KM-2104, KM-2105, KM-2119	IIa
	Venturi Oxygen Masks: KM-131, KM-132, KM-133, KM-134, KM-908A, KM-237	IIa
	Breathing Circuit: KM-993, KM-994, KM-993A, KM-994A, KM-995, KM-996, KM-995A, KM-996A, KM-990, KM-991, K- CFES, K- CFE, K- DCFE, K- CES, K- CFEW, K- CEW, KM-997, KM-997A, KM-294, KM-295, KM-294A, KM-295A	IIa
	Fisiojet Line, including: Fisio Chamber: KM-1014, KM-1015, KM-1016, KM-1017, KM-1018, KM-1020, KM-1021, KM-1022, KM-1023A, KM-1026, KM-1020B, KM-1021B, KM-1022B, KM-1321B, KM-1322B, KM-1030, KM-1031, KM-1032, KM-1030B, KM-1031B, KM-1032B, KM-1033B Fisiojet Mask: KM-1005, KM-1006, KM-1007, KM-1008, KM-1023, KM-1024, KM-1025 Panda Mask: KM-1033, KM-1034, KM-1035, KM-1036 Small Volume Nebulizer: KM-111, KM-112, KM-113, KM-114, KM-115, KM-119, KM-113A, KM-114A	IIa

	Aerosol Therapy: KM-1000, KM-1001, KM-1002,KM-1003, KM-1004, KM-1000A, KM-1001A, KM-1002A, KM-1003A, KM-1000B, KM-1001B, KM-1002B, KM-1003B, KM-1000C, KM-1001C, KM-1002C, KM-1003C	

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
KOO (Shanghai) Industries Co., Ltd.	100 Zhongde Road, Xiaokunshan Town, Songjiang, Shanghai 201614, P.R. China

EU Representative
Koo Europe s.r.l., Viale delle Industrie 5, 20020 Arese (Mi), ITALY.

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate

CE SERTIFIKATAS
PILNA PRODUKTO KOKYBĖS UŽTIKRINIMO SISTEMA

Sertifikato Nr.:	Projekto Nr.:	Galioja iki:
10016-2017-CE-RGC-NA-PS Perž.1.0	PRJC-523132-2015-PRC-CHN	2024-05-26

Šis sertifikatas patvirtina, kad Kokybės vadybos sistema

Koo (Shanghai) Industries Co., Ltd.

100 Zhongde Road, Xiaokunshan Town, Songjiang, Shanghai 201614, Kinija

projektavimui, gamybai ir galutiniam produkto patikrinimui/testavimui buvo pripažinta atitinkanti, žemiau nurodytiems produktams:

Sterilios ir nesterilios medicininės priemonės anestezijai, kvėpavimui ir kritiniams atvejams

Įvertinimas buvo atliktas pagal įvertinimo procedūrą, pateiktą Medicinos priemonių direktyvos 93/42/EEB II priede, išskyrus 4 skirsnį

Platesnė informacija yra pateikiama kitame lape

Vieta ir data:

Høvik, 2020 m. liepos 7 d.

NORWEGIAN ACCREDITATION

PROD 021

DNV GL PRESAFE AS

Notifikuotoji įstaiga Nr: 2460

Eugenie Winger Husebye

Sertifikato Nr.:	Projekto Nr.:	Galioja iki:
10016-2017-CE-RGC-NA-PS Perž.1.0	PRJC-523132-2015-PRC-CHN	2024-05-26

Jurisdikcija

Tarybos direktyvos prašymas 93/42/EEC 1993 m. birželio 14 d., Norvegijos Sveikatos ir socialinių reikalų ministerijos adaptuotas kaip „Forskrift for Medisinsk Utstyr“.

Sertifikato istorija

Peržiūrėjimas	Aprašymas	Išleidimo data
0.0	Originalus sertifikatas	2017-05-31
1.0	Pakartotinis sertifikavimas	2020-07-07

Šiuo sertifikatu pažymėti produktai:

Produkto aprašymas	Produkto pavadinimas	Klasė
Sterilios medicininės priemonės anestezijai, kvėpavimui ir kritiniams atvejams	Crystal laringinės kaukės: KM-817, KM-827, KM-837,KM-847, KM-857, KM-867, KM-877 Crystal laringinės kaukės-Contour Crystal laringinės kaukės-Contour Plus Flex CAM armuotos laringinės kaukės	IIa
Nesterilios medicininės priemonės anestezijai, kvėpavimui ir kritiniams atvejams	Anestezinė veido kaukė Deguonies kaukė Kvėpavimo treniruokliai Deguonies kaniulė Venturi deguonies kaukė Kvėpavimo kontūrai Fisiojet linijos aerozolinės terapijos produktai	IIa

Pilnas priemonių sąrašas yra pildomas Notifikuotos įstaigos

Vietos, kurias apima šis sertifikatas:

Vietos pavadinimas	Adresas
Koo Shanghai Industries Co., Ltd.	100 Zhongde Road, Xiaokunshan Town, Songjiang, Shanghai 201614, Kinija

Sertifikato Nr.:	Projekto Nr.:	Galioja iki:
10016-2017-CE-RGC-NA-PS Perž.1.0	PRJC-523132-2015-PRC-CHN	2024-05-26

ES atstovas

Koo Europe s.r.l.,

Viale delle Industie 5, 20020 Arese (Mi), Italija

Terminai ir sąlygos

Šis sertifikatas pavaldus šiems terminams ir sąlygoms:

- Remiantis 85/374/EEC direktyvos pataisos dėl defektinių produktų atsakomybės, bet kuris gamintojas (tikslus apibrėžimas žr. 2001/95/CE) yra atsakingas už žalą, padarytą dėl jo produkto(ų) defektų.
- Šis sertifikatas galioja tik tiems produktams ir/ar gamykloms, kurios išvardytos aukščiau.
- Gamintojas turi vykdyti visus įsipareigojimus, pateikiamus kokybės sistemos, kaip yra nustatyta, ir laikytis jų taip, kad jie išliktų adekvatūs ir efektyvūs.
- Gamintojas turi informuoti vietinę DNV atstovybę dėl ketinimo atnaujinti kokybės sistemą, o DNV turi įvertinti pakeitimus ir nuspręsti, ar sertifikatas išliks galioti.
- Turi būti atliekami periodiniai auditai nustatyti, ar gamintojas laikosi ir taiko kokybės sistemą, o DNV turi teisę čia pat vietoje atlikti auditą be išankstinio perspėjimo ar dėl įtarimo.

Sertifikatas gali nustoti galioti dėl:

- Gamybai įtakos turinčių kokybės sistemos pakeitimų.
- Per leistiną laikotarpį netlikus periodinių auditų.

Atitikties deklaracija ir produkto žymėjimas
Atitikus aukščiau paminėtus terminus ir sąlygas, gamintojas turi teisę sudaryti CE atitikties deklaraciją ir legaliai priskirti CE ženklą pagal Notifikuotos institucijos DNV identifikacijos numerį.

SERTIFIKATO PABAIGA

KDOC2001 Ver. A

Declaration of Conformity

For the following products:
Laryngeal mask: Crystal Airway Mask, Flex CAM, Crystal Airway Mask-Contour，Crystal Airway Mask-Contour Plus; Class IIA.

(Model Designation)

is hereinafter confirmed to comply with the requirements set out in the Council Directive on the harmonization of the Laws of the Member States concerning Medical Device Directive (93/42/EEC As amended by 2007/47/EC)

Applicable harmonized standards are:

EN ISO 13485:2016	EN ISO 14971:2012	EN ISO10993-1:2009	EN ISO 10993-5:2009
EN ISO 10993-7:2008	EN ISO 10993-10:2009	EN ISO 11135-1:2007	EN ISO 11607-1:2009
EN ISO 11607-2:2006	EN ISO 11737-1:2006	EN ISO 11737-2:2009	EN 62366:2008
EN ISO 5356-1:2015	EN 1041:2008	EN 20594-1:1993	EN ISO15223-1:2016

Conformity Assessment Route:
Annex II excluding section 4 of Medical Device Directive

Notified Body:
DNV GL Presafe AS (NB No. 2460)
Veritasveien 3, 1363 Høvik, Norway

The following European Authorized Representative is stated to the declaration:
Company Name: Koo Europe s.r.l.
Company Address: Viale delle Industrie 5, 20020 Arese (MI), ITALY

The following manufacturer is exclusively responsible for making this declaration:
Company Name: KOO (Shanghai) Industries Co., Ltd.
Company Address: 100 Zhongde Road,Dakun Industrial Park,Songjiang,Shanghai 201614, P.R.CHINA

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Device list:

NO.	Product Description	Product Code	Size
1	Crystal Airway Mask-SIZE 5	KM-817	5#
2	Crystal Airway Mask-SIZE 4	KM-827	4#
3	Crystal Airway Mask-SIZE 3	KM-837	3#
4	Crystal Airway Mask-SIZE 2.5	KM-847	2.5#
5	Crystal Airway Mask-SIZE 2	KM-857	2#
6	Crystal Airway Mask-SIZE 1.5	KM-867	1.5#
7	Crystal Airway Mask-SIZE 1	KM-877	1#
8	Crystal Airway Mask-Contour (with angle)-SIZE 6	KM-816	6#
9	Crystal Airway Mask-Contour (with angle)-SIZE 5	KM-826	5#
10	Crystal Airway Mask-Contour (with angle)-SIZE 4	KM-836	4#
11	Crystal Airway Mask-Contour (with angle)-SIZE 3	KM-846	3#
12	Crystal Airway Mask-Contour (with angle)-SIZE 2.5	KM-856	2.5#
13	Crystal Airway Mask-Contour (with angle)-SIZE 2	KM-866	2#
14	Crystal Airway Mask-Contour (with angle)-SIZE 1.5	KM-876	1.5#
15	Crystal Airway Mask-Contour (with angle)-SIZE 1	KM-886	1#
16	Crystal Airway Mask-Contour Plus (with Angle and Suction)-SIZE 6	KM-815	6#
17	Crystal Airway Mask-Contour Plus (with Angle and Suction)-SIZE 5	KM-825	5#
18	Crystal Airway Mask-Contour Plus (with Angle and Suction)-SIZE 4	KM-835	4#
19	Crystal Airway Mask-Contour Plus (with Angle and Suction)-SIZE 3	KM-845	3#
20	Crystal Airway Mask-Contour Plus (with Angle and Suction)-SIZE 2.5	KM-855	2.5#
21	Crystal Airway Mask-Contour Plus (with Angle and Suction)-SIZE 2	KM-865	2#
22	Crystal Airway Mask-Contour Plus (with Angle and Suction)-SIZE 1.5	KM-875	1.5#
23	Crystal Airway Mask-Contour Plus (with Angle and Suction)-SIZE 1	KM-885	1#
24	Flexible Crystal Airway Mask (Flex CAM) -SIZE 5	KM-818	5#
25	Flexible Crystal Airway Mask (Flex CAM) -SIZE 4	KM-828	4#
26	Flexible Crystal Airway Mask (Flex CAM) -SIZE 3	KM-838	3#
27	Flexible Crystal Airway Mask (Flex CAM) -SIZE 2.5	KM-848	2.5#
28	Flexible Crystal Airway Mask (Flex CAM) -SIZE 2	KM-858	2#

Change history

Version	Description	Date	Editor	Approval
A	New release	2019-06-03	Shosho.Shao	Steve Saad

KDOC2001 Patv. A

Atitikties Deklaracija

Žemiau nurodytiems produktams:
Laringinės kaukės: Crystal laringinė kaukė, Flex armuotos laringinė kaukėCCVVAM, Crystal laringinė kaukė-Contour, Crystal laringinė kaukė-Contour Plius: Ila klasė.

Patvirtinama, kad Atitikties Deklaracija laikosi Tarybos Direktyvos, valstybių narių įstatymų, atsižvelgiant į Medicininių priemonių Direktyvą 93/42/EEB.

Taikomi standartai:

EN ISO 13485:2016	EN ISO 14971:2012	EN 1S010993-1:2009	EN ISO 10993-5:2009
EN ISO 10993-7:2008	EN ISO 10993-10:2009	EN ISO 11135-1:2007	EN ISO 11607-1:2009
EN ISO 11607-2:2006	EN ISO 11737-1:2006	EN ISO 11737-2:2009	EN 62366:2008
EN ISO 5356-1:2015	EN 1041:2008	EN 20594-1:1993	EN ISO15223-1:2016

Atitikties Deklaracijos vertinimas pagal:
Medicininių priemonių Direktyvos II Priedą, išskyrus 4 skirsnį

Notifikuotoji įstaiga:
DNVGL Presafe AS {NB No. 2460)
Veritasveien 3, 1363 H121vik, Norvegija

Įgaliotasis atstovas Europoje:

Kompanija: **Koo Europe s.r.l.**
Adresas: **Viale delle Industrie 5, 20020 Arese (MI), Italija**

Gamintojas, kuriam taikoma ši Deklaracija:

Kompanija: KOO (Shanghai) Industries Co., Ltd.
Adresas: 100 Zhongde Road,Dakun Industrial Park,Songjiang,Shanghai 201614, Kinij

	Vyriausias vadybininkas	2019-06-05
Parašas	Pareigos	Data

Priemonių sąrašas

Nr.	Aprašymas	Produkto kodas	Dydis
1	Crystal laringinė kaukė- dydis 5	KM-817	5#
2	Crystal laringinė kaukė- dydis 4	KM-827	4#
3	Crystal laringinė kaukė- dydis 3	KM-837	3#
4	Crystal laringinė kaukė- dydis 2.5	KM-847	2.5#
5	Crystal laringinė kaukė- dydis 2	KM-857	2#
6	Crystal laringinė kaukė- dydis 1.5	KM-867	1.5#
7	Crystal laringinė kaukė- dydis 1	KM- 877	1#
8	Crystal laringinė kaukė- Contour- dydis 6	KM-816	6#
9	Crystal laringinė kaukė- Contour- dydis 5	KM-826	5#
10	Crystal laringinė kaukė- Contour- dydis 4	KM-836	4#
11	Crystal laringinė kaukė- Contour- dydis 3	KM-846	3#
12	Crystal laringinė kaukė- Contour- dydis 2.5	KM-856	2.5#
13	Crystal laringinė kaukė- Contour- dydis 2	KM-866	2#
14	Crystal laringinė kaukė- Contour- dydis 1.5	KM-876	1.5#
15	Crystal laringinė kaukė- Contour- dydis 1	KM-856	1#
16	Crystal laringinė kaukė- Contour Plius- dydis 6	KM-815	6#
17	Crystal laringinė kaukė- Contour Plius- dydis 5	KM-825	5#
18	Crystal laringinė kaukė- Contour Plius- dydis 4	KM-835	4#
19	Crystal laringinė kaukė- Contour Plius- dydis 3	KM-845	3#
20	Crystal laringinė kaukė- Contour Plius- dydis 2.5	KM-855	2.5#
21	Crystal laringinė kaukė- Contour Plius- dydis 2	KM-865	2#
22	Crystal laringinė kaukė- Contour Plius- dydis 1.5	KM-875	1.5#
23	Crystal laringinė kaukė- Contour Plius- dydis 1	KM-885	1#
24	Lanksti armuota Crystal laringinė kaukė (Flex CAM)- dydis 5	KM-818	5#
25	Lanksti armuota Crystal laringinė kaukė (Flex CAM)- dydis 4	KM-828	4#
26	Lanksti armuota Crystal laringinė kaukė (Flex CAM)- dydis 3	KM-838	3#
27	Lanksti armuota Crystal laringinė kaukė (Flex CAM)- dydis 2.5	KM-848	2.5#
28	Lanksti armuota Crystal laringinė kaukė (Flex CAM)- dydis 2	KM-858	2#

Istorija:

Versija	Aprašymas	Data	Redaktorius	Patvirtino
A	Naujas leidimas	2019-06-03	Shosho.Shao	Steve Saad

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 540595**

Issued To: **Teleflex Medical**
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland

In respect of:

The design and manufacture of non active digestive tract devices; non active gynecological devices; non active regional anaesthesia devices; non active respiratory devices; non active surgical devices; non active urology devices.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2009-01-13** Date: **2020-06-09** Expiry Date: **2024-05-26**

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EC Certificate - Full Quality Assurance System

Supplementary Information to CE 540595

Issued To:

Teleflex Medical
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland

Number	Device Name	Intended purpose per IFU
Class III		
---	EpiStar CSE - Spinal-Epidural Anaesthesia Kits	See CE 544836
---	Spinostar Spinal Needles	See CE 560441
Class IIb		
10735	Sterile Percutaneous Nephrostomy Catheter	Puncture and dilation of percutaneous approaches into the upper urinary tract.
35404	Sterile Tracheostomy Tube	Cannulation of tracheostomised patients through an existing tracheostoma.
14099	Sterile Tracheostomy Tube	Cannulation of tracheostomised patients, in whom the stoma was created by percutaneous dilative tracheostomy.
58005	Sterile Ureter Stent	Routine drainage of the renal pelvis via the ureter or a ureter-skin stoma to an external collection site.
34924	Sterile Suprapubic Cystotomy Set	Routine suprapubic drainage of the bladder
31074	Sterile Ureterocutaneostomy Catheter	Routine drainage of urine through a ureterocutaneous stoma site.

First Issued: **2009-01-13** Date: **2020-06-09** Expiry Date: **2024-05-26**

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 540595

Issued To:

Teleflex Medical
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland

Number	Device Name	Intended purpose per IFU
Class IIa		
MD 0106	Sterile Transurethral Catheter	---
MD 0101	Sterile Tracheostomy Retainer Set	---
MD 0106	Sterile Rectal Tube	---
MD 0101 MD 1102	Sterile Breathing Circuit	---
MD 0101 MD 1102	Non-sterile Breathing Circuit	
MD 0101	Sterile Cricothyrotomy Set	---
MD 0102	Sterile Epidural Set	---
MD 0101	Sterile EZ Blocker Kit	---
MD 0106	Sterile Guidewire	---
MD 0106	Sterile Kidney Stone Extractor	---
MD 0101	Sterile Tracheal Tube	---
MD 0101	Non-sterile Tracheal Tube	---
MD 0101	Sterile Laryngeal Mask	---
MD 0101	Non-sterile Laryngeal Mask	---

First Issued: **2009-01-13** Date: **2020-06-09** Expiry Date: **2024-05-26**

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 540595

Issued To:

Teleflex Medical
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland

Number	Device Name	Intended purpose per IFU
Class IIa		
MD 0106	Sterile Laparoscopy Bag	---
MD 0101	Sterile Bronchial Tube	---
MD 0101	Sterile Suprapubic Cystotomy Set	---
MD 0303	Sterile Drainage Tube	---
MD 0101	Sterile Tracheostomy Tube, Inner cannula	---
MD 0106	Sterile Ureter Catheter	---
MD 0102	Sterile Needle Introducer	---
MD 0101	Sterile Percutaneous Nephrostomy Catheter	---
MD 0106	Non-sterile Temperature Sensor	---
MD 0101	Sterile Breathing Bag	---
MD 0101 MD 0106	Sterile Irrigation System for Ureterocutaneostomy	---

First Issued: **2009-01-13** Date: **2020-06-09** Expiry Date: **2024-05-26**

By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 540595**
Date:	**2020-06-09**
Issued To:	**Teleflex Medical** **IDA Business and Technology Park** **Dublin Road** **Athlone** **Co. Westmeath** **Ireland**

Subcontractor:	**Service(s) supplied**
Arrow International CR, a.s. Jamska 2359/47 Zdar Nad Sazavou 59101 Czech Republic	**Design** **Manufacture**
Arrow International CR, a.s. Prazska 209 Hradec Kralove 50004 Czech Republic	**Design**
Arrow Medical Ltd Hatton Garden Industrial Estate Kington Hereford HR5 3RB United Kingdom	**Manufacture**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 540595**
Date:	**2020-06-09**
Issued To:	**Teleflex Medical** **IDA Business and Technology Park** **Dublin Road** **Athlone** **Co. Westmeath** **Ireland**

Subcontractor:	**Service(s) supplied**
BBF Sterilisationsservice GmbH Willy-Rüsch-Straße 10/1 71394 Kernen Germany	**Radiation (Gamma Sterilization)**
Chelle Medical Limited Le Rocher P.O Box 221 Victoria Mahe Seychelles	**Manufacture**
Chemiczna Spółdzielnia Pracy Technochemia ul. Fabryczna 3 05-600 Grójec Poland	**ETO Sterilization**
Contract Medical International, spol. sr.o. Vážní 848 500 03 Hradec Králové Czech Republic	**Manufacture**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 540595**
Date:	**2020-06-09**
Issued To:	**Teleflex Medical** **IDA Business and Technology Park** **Dublin Road** **Athlone** **Co. Westmeath** **Ireland**

Subcontractor:	**Service(s) supplied**
Daqing Medical Device (Tianjin) Co., Ltd 10A & 11A Tianzhi Industrial Center No.12 Hong Yuan Road Xiqing Economic Development Area 300385 Tianjin People's Republic of China	**Manufacture**
Degania Silicone Limited Kibbutz 1513000 Degania Bet Israel	**Manufacture**
Forefront (Xiamen) Medical Devices Co., Ltd No. 28 Haijing East Road & No. 61 Haijing South Road Xiamen Area of China (Fujian) Pilot Free Trade Zone 361026 Xiamen, Fujian People's Republic of China	**Manufacture**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 540595**
Date:	**2020-06-09**
Issued To:	**Teleflex Medical** **IDA Business and Technology Park** **Dublin Road** **Athlone** **Co. Westmeath** **Ireland**

Subcontractor:	**Service(s) supplied**
Forefront Medical Technology (Pte) Ltd 35 Joo Koon Circle Singapore 629110 Singapore	**Manufacture**
M.E.M., Inc. 8 Bishop Lane Madison Connecticut 06443 USA	**Manufacture**
Medicoplast International GmbH Heusweilerstrasse 100 DE-66557 Illingen Germany	**ETO Sterilization**
Parker Hannifin CSS Merrillville 1201 East 86th Place Merrillville IN, 46410 United States	**Manufacture**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 540595**
Date:	**2020-06-09**
Issued To:	**Teleflex Medical** **IDA Business and Technology Park** **Dublin Road** **Athlone** **Co. Westmeath** **Ireland**

Subcontractor:	**Service(s) supplied**
Plaxtron Industrial (M) Sdn. Bhd. Plot 28, Kawasan Perusahaan Jelapang II Zon Perdagangan Bebas, Ipoh Perak 30020 Malaysia	**Manufacture**
Professional Contract Sterilization Inc. 40 Myles Standish Blvd Taunton Massachusetts 02780-1026 USA	**ETO Sterilization**
safemed medical devices s.r.o Trabantská 292 19015 Praha 9 Czech Republic	**Manufacture**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 540595**
Date:	**2020-06-09**
Issued To:	**Teleflex Medical** **IDA Business and Technology Park** **Dublin Road** **Athlone** **Co. Westmeath** **Ireland**

Subcontractor:	**Service(s) supplied**
sfm medical devices GmbH Brückenstraße 5 63607 Wächtersbach Germany	**ETO Sterilization** **Manufacture**
SINA-SterilGamma Sdn. Bhd. LOT 88077, Jalan Perigi Nenas 7/1 Taman Perindustrian Pulau Indah 42907 Pelabuhan Klang. Selangor Malaysia	**ETO Sterilization**
SP Medical A/S Møllevej 1 4653 Karise Denmark	**Design** **Manufacture**
SP Medical Sp. z o.o. UI. Ceramiczna 2K 98-220 Zduńska Wola Poland	**Manufacture**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 540595**
Date:	**2020-06-09**
Issued To:	**Teleflex Medical** **IDA Business and Technology Park** **Dublin Road** **Athlone** **Co. Westmeath** **Ireland**

Subcontractor:	**Service(s) supplied**
STERIS AST CZ s.r.o. Prumyslová Zona Kosikov 80 Velka Bites 59501 Czech Republic	**ETO Sterilization**
Synergy Sterilisation (M) Sdn Bhd. Plot 203 Kuala Ketil Industrial Estate Kuala Ketil Kedah 09300 Malaysia	**ETO Sterilization**
Synergy Sterilisation Kulim (M) Sdn. Bhd Lot 71, Kulim Industrial Estate Kulim Kedah 09000 Malaysia	**ETO Sterilization**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 540595**
Date:	**2020-06-09**
Issued To:	**Teleflex Medical** **IDA Business and Technology Park** **Dublin Road** **Athlone** **Co. Westmeath** **Ireland**

Subcontractor:	**Service(s) supplied**
Teleflex Medical Asia Pte. Ltd. 21 Merchant Road #04-01 Royal Merukh S.E.A 058267 Singapore	**Design** **Manufacture**
Teleflex Medical Sdn. Bhd. Lot PT 2577, Jalan Perusahaan 4 34600 Kamunting Perak Malaysia	**Design** **ETO Sterilization** **Manufacture**
The Laryngeal Mask Company (Malaysia) Sdn. Bhd. Lot 19 & 1920 Industrial Zone Phase 1 Kulim Hi-Tech Park Kulim 09000 Malaysia	**Manufacture**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 540595**

Date: **2020-06-09**

Issued To: **Teleflex Medical**
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland

Date	Reference Number	Action
13 January 2009	7245725	First issue.
17 March 2009	7325719	Company address amended. Extension to scope. Addition of Willy Rüsch, Germany as subcontractor for design and manufacture.
25 August 2009	7399879	Addition of 'epidural catheter Epistar and Epistar CSE' to scope. Addition of SFM as significant subcontractor for manufacture. Addition of 'design' to services supplied by Teleflex Medical Malaysia, Arrow International CR, a.s. and Arrow International Inc., Czech Republic.
11 November 2009	7455515	Addition of CeMed GmbH for manufacturing to the list of significant subcontractors.
20 April 2010	7497906	Laryngeal Mask added to scope. Addition of Tianjin Medis Medical Device Co. Ltd as significant subcontractor for manufacture.
08 September 2010	7558508	Scope reworded in accordance with generic device groups. Certificate renewal.
23 May 2012	7778467	Correction of significant subcontractor address and addition of new scope activities for subcontractors.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 540595**
Date: **2020-06-09**
Issued To: **Teleflex Medical**
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland

Date	Reference Number	Action
04 February 2013	7932588	The addition of a significant subcontractor SP Medical A/S.
14 May 2014	8134266	Addition of peripheral angioplasty balloon catheters to product family, covered by scope expression 'non-active surgical devices'. Addition of significant subcontractors Hotspur Technologies, Inc and Teleflex Medical Asia Pte Ltd.
09 March 2015	8293488	Addition of 8 crucial suppliers.
28 August 2015	8406490	Certificate renewal. Removal of Hotspur Technologies, Inc. from list of significant subcontractors.
05 August 2016	8571081	Addition of Contract Medical International, spol. sr.o. to the list of significant subcontractors. Addition of EZ Blocker non-active respiratory device.
09 January 2017	8665617	Change to the address of subcontractor (Forefront).
16 July 2018	8939923	Addition of Daqing Medical Device (Tianjin) Co., Ltd to the list of significant subcontractors.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 540595**

Date: **2020-06-09**

Issued To: **Teleflex Medical**
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland

Date	Reference Number	Action
4 March 2019	7779566	Traceable to NB 0086.
Current	3124666	Certificate renewal. Addition of supplementary product information table. Removal of Control of Sterilization from Service(s) supplied for Arrow International CR, a.s. (Zdar), Arrow International CR, a.s. (Hradec Kralove), Contract Medical International spol. sr.o., SP Medical A/S, sfm medical devices GmbH, Teleflex Medical Asia Pte. Ltd. and Teleflex Medical Sdn. Bhd. Removal of Crucial Supplier from Service(s) supplied for Arrow Medical Ltd, Chelle Medical Limited, Forefront (Xiamen) Medical Devices Co., Ltd, Forefront Medical Technology (Pte) Ltd, Parker Hannifin CSS Merrillville, Plaxtron Industrial (M) Sdn. Bhd. and The Laryngeal Mask Company (Malaysia) Sdn. Bhd. Addition of Manufacture to Service(s) supplied for Arrow Medical Ltd, Chelle Medical Limited, Forefront (Xiamen) Medical Devices Co., Ltd, Forefront Medical Technology (Pte) Ltd, M.E.M., Inc., Parker Hannifin CSS Merrillville, Plaxtron Industrial (M) Sdn. Bhd., and The Laryngeal Mask Company (Malaysia) Sdn. Bhd. Removal of Manufacture from Service(s) supplied for Arrow International CR, a.s. (Hradec Kralove) Addition of Degania Silicone Limited, safemed medical devices s.r.o and SP Medical Sp. z.o.o. as subcontractors for Manufacture.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 540595**

Date: **2020-06-09**

Issued To: **Teleflex Medical**
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland

Date	Reference Number	Action
		Addition of STERIS AST CZ s.r.o., Synergy Sterilisation (M) Sdn Bhd., Synergy Sterilisation Kulim (M) Sdn Bhd., Chemiczna Spółdzieknia, Medicoplast International GmbH, Professional Contract Sterilization Inc., SINA-SterilGamma Sdn Bhd and Teleflex Medical Sdn. Bhd. as subcontractors for ETO Sterilization. Addition of BBF Sterilisationsservice GmbH as subcontractor for Gamma Sterilization. Removal of CeMed GmbH, Tianjin Medis Medical and Willy Rüsch GmbH Administrative correction of details for Arrow Medical Ltd, Chelle Medical Limited, Contract Medical International spol. sr.o., Daqing Medical Device (Tianjin) Co., Ltd, Forefront (Xiamen) Medical Devices Co., Ltd and SP Medical A/S. Change of address for Teleflex Medical Asia Pte. Ltd. Name change from Süddeutsche Feinmechanik GmbH (SFM) to sfm medical devices GmbH Name change from Parker Medical Systems Division - Merrillville to Parker Hannifin CSS Merrillville

CE Sertifikatas – Visiškos kokybės užtkrinimo sistema

Medicininių prietaisų Direktyva 93/42/EEB, II priedas, išskyrus 4 skirsnį

Nr. **CE 540595**

Išduota: **Teleflex Medical**
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
AIRIJA

Dėl:

neaktyvių virškinamojo trakto, ginekologinių, regioninės anestezijos, kvėpavimo, chirurginių, urologinių priemonių dizaino ir gamybos.

Atsižvelgiant į mūsų atliktą kokybės užtikrinimo sistemos apžiūrą pagal Tarybos direktyvos 93/42/EEC II priedo, išskyrus 4 skyrių, reikalavimus. Kokybės užtikrinimo sistema atitinka direktyvos keliamus reikalavimus. Norint rinkoje pardavinėti III klasės produktus, reikalingas II priedo 4 skyriaus sertifikatas.

BSI vardu, Notifikuojanti institucija dėl minėtos Direktyvos (Notifikuojančios institucijos Nr. 0086):

G , viceprezidentas priemonėms

Pirmas leidimas: **2009-01-13** Data: **2020-06-09** Galioja iki: **2024-05-26**

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CE Sertifikatas – Visiškos kokybės užtkrinimo sistema

Papildoma informacija prie CE 540595

Išduota:

Teleflex Medical
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Airija

Numeris	Priemonės pavadinimas	Numatyta naudojimo sritis, pagal naudojimosi instrukciją
III klasė		
---	EpiStar CSE – Spinalinės epidūrinės anestezijos rinkiniai	Žiūrėti CE 544836
---	Spinostar spinalinės adatos	Žiūrėti CE 560441
IIb klasė		
10735	Sterilus perkutaninės nefrostomijos kateteris	Viršutinių šlapimo takų punkcijai ir plėtimui perkutaniniu būdu.
35404	Sterilus tracheostominis vamzdelis	Tracheostominių pacientų kaniuliacijai per esamą tracheostoma.
14099	Sterilus tracheostominis vamzdelis	Tracheostominių pacientų, kuriems stoma buvo suformuota perkutaniniu būdu, kaniuliacijai.
58005	Sterilus ureterinis stentas	Įprastiniam inksto drenavimui per šlapimtakį ar šlapimtakio-odos stoma į išorinę surinkimo vietą.
34924	Sterilus suprapubinės cistostomijos rinkinys	Įprastiniam suprapubiniam šlapimo pūslės drenavimui.
31074	Sterilus ureterokutaneostomijos kateteris	Įprastiniam šlapimo drenavimui per šlapimtakio stoma.

Pirmas leidimas: **2009-01-13** Data: **2020-06-09** Galioja iki: **2024-05-26**

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CE Sertifikatas – Visiškos kokybės užtkrinimo sistema

Papildoma informacija prie CE 540595

Išduota:

Teleflex Medical
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Airija

Numeris	Priemonės pavadinimas	Numatyta naudojimo sritis, pagal naudojimosi instrukciją
IIa klasė		
MD 0106	Sterilus transuretrinis kateteris	---
MD 0101	Sterlus tracheostomijos laikiklių rinkinys	---
MD 0106	Sterilus rektalinis vamzdelis	---
MD 0101 MD 1102	Sterilus kvėpavimo kontūras	---
MD 0101 MD 1102	Nesterilus kvėpavimo kontūras	
MD 0101	Sterilus krikotirotomijos rinkinys	---
MD 0102	Sterilus epidūrinis rinkinys	---
MD 0101	Sterilus EZ blokavimo rinkinys	---
MD 0106	Sterili viela-pravedėjas	---
MD 0106	Sterilus inkstų akmenų ištraukėjas	---
MD 0101	Sterilus trachėjinis vamzdelis	---
MD 0101	Nesterilus trachėjinis vamzdelis	---
MD 0101	Sterili laringinė kaukė	---
MD 0101	Nesterili laringinė kaukė	---

Pirmas leidimas: **2009-01-13** Data: **2020-06-09** Galioja iki: **2024-05-26**

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CE Sertifikatas – Visiškos kokybės užtkrinimo sistema

Papildoma informacija prie CE 540595

Išduota:

Teleflex Medical
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Airija

Numeris	Priemonės pavadinimas	Numatyta naudojimo sritis, pagal naudojimosi instrukciją
IIa klasė		
MD 0106	Sterilus laparoskopinis maišelis	---
MD 0101	Sterilus bronchų vamzdelis	---
MD 0101	Sterilus suprapubinės cistostomijos rinkinys	---
MD 0303	Sterilus drenavmo vamzdelis	---
MD 0101	Sterilus tracheostominis vamzdelis, vidinė kaniulė	---
MD 0106	Sterilus ureterinis kateteris	---
MD 0102	Sterili įvedimo adata	---
MD 0101	Sterilus perkutaninės nefrostomijos kateteris	---
MD 0106	Nesterilus temperatūros jutiklis	---
MD 0101	Sterilus kėpavimo maišas	---
MD 0101 MD 0106	Sterili drėkinimo Sistema ureterokutaneostomijai	---

Pirmas leidimas: **2009-01-13** Data: **2020-06-09** Galioja iki: **2024-05-26**

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May 20th , 2024

C/0390/24/GF/mm

To: LUMED S.r.l.
Via Vittor Pisani, 28
20124 - Milano, (MI)

Bureau Veritas Italia SpA

Notified Body Confirmation Letter with reference to the CE Marking **Certificate n° MED 26032 rev.10 - Directive 93/42/EEC (MDD)**

This letter confirms that, Bureau Veritas Italia SpA, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1370 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement n. 5209721 rev.3 in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

LUMED S.r.l.
Via Vittor Pisani, 28
20124 - Milano, (MI)
Italia

Tabella n.1

Device name or Basic UDI-DI (under MDR application)	**MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)**	**Device name under MDD corresponding to the device under MDR application**	**MDD/AIMDD Certificate Reference(s) of the devices under MDR application**
BOCCAGLI	IIa	Boccagli / Mouthpieces	Certificate n° MED 26032 rev.10 issued by NB KIWA identified by n. 0476 on 2021/05/24
FILTRI B.V. (Batterici Virali)	IIa	Filtri B.V. (batterici – virali) Bacterial-viral filters	Certificate n° MED 26032 rev.10 issued by NB KIWA identified by n. 0476 on 2021/05/24
Boccaglio con filtro per Spirometria (BOFAP)	IIa	Boccagli con filtro antiparticolato / Mouthpieces with particulate filter	Certificate n° MED 26032 rev.10 issued by NB KIWA identified by n. 0476 on 2021/05/24
Elettrocardiografi di seconda generazione	IIa	Elettrocardiografi di seconda generazione / Electrocardiographs	Certificate n° MED 26032 rev.10 issued by NB KIWA identified by n. 0476 on 2021/05/24
Holter ECG	IIa	Holter ECG / Holter systems	Certificate n° MED 26032 rev.10 issued by NB KIWA identified by n. 0476 on 2021/05/24
Carte di registrazione per apparecchiature	Im	Carte di registrazione per apparecchiature	Certificate n° MED 26032 rev.10 issued by NB KIWA

elettromedicali		elettromedicali / Recording chart paper for medical devices	identified by n. 0476 on 2021/05/24

In accordance with EU Regulation 2023/607 of the European Parliament of the Council of 15 March 2023, Bureau Veritas Italia hereby confirms that:

a. The above-mentioned agreement n. 5209721 rev.3 was signed within 2024/09/26.
b. Bureau Veritas Italia Spa is not responsible for the appropriate surveillance of medical devices certified under Directive 93/42/EEC and subsequent amendments, corresponding to medical devices for which an agreement has been signed for certification according to EU Regulation 2017/745 (MDR) as shown in table n.1

As required by EU Regulation 2023/607, the validity of the MDD certificate n° **MED 26032 rev.10** is extended until 2028/12/31, assuming that the manufacturer continues to comply with all the applicable conditions specified by EU Regulation 2023/607.

Confirmation Letter Revision History

Date	Revision	Action
2024/05/20	0	Initial issue

GLORIA FOCETOLA - Local Technical Manager

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Cap. Soc. € 4.472.131,00 i.v.
Reg. Imp. e P.IVA 11498640157
Altre Sedi: www.bureauveritas.it/sedi

Soggetta all'attività di direzione e coordinamento da parte di Bureau Veritas SA con sede in Neuilly-sur-Seine - Francia

CERTIFICATE

Reg. Numero / *Reg. Number*	MED 26032	Revisione / *Revision*	10
Primo rilascio / *First issue date*	2006-09-07	Valido da / *Valid from*	2021-05-24
Scadenza / *Valid until*	2024-05-26	Ultima modifica / *Last change date*	2021-05-24

Certificato CE del Sistema di Garanzia della Qualità
EC Quality Assurance System Certificate

Si certifica che, sulla base dei risultati degli audit effettuati, il Sistema di garanzia di Qualità della Produzione dell'Organizzazione/ *We certify that, on the basis of the audits carried out, the Production Quality Assurance System of the Organization:*

LUMED S.r.l.

Sede Operativa / *Operational Headquarter:*
Via Staffora, 18/9
20073 Opera, MI - Italia

Sede legale / *Registered Headquarter*
Via Vittor Pisani, 28
20124 Milano, MI - Italia

Sede Operativa / *Operational Headquarter*
Via Senio, 36/40
47121 Forlì, FC - Italia

è conforme ai requisiti applicabili della Direttiva 93/42/CEE e successive modifiche ed integrazioni, Allegato V, attuata in Italia con Dlgs. 46 del 1997/02/24 e successive modifiche ed integrazioni per le seguenti tipologie di Dispositivi Medici / *Is in compliance with the applicable requirements of 93/42/EEC Directive as amended, Annex V, transposed in Italy by Dlgs. 46 of 1997/02/24 as amended for the following Medical Devices:*

Carte di registrazione per apparecchiature elettromedicali / *Recording chart paper for medical devices*
Dispositivi monouso per diagnostica polmonare / *Disposable devices for pulmonary test*
Elettrocardiografi / *Electrocardiographs*
Elettrocardiografi di seconda generazione / *Electrocardiographs*
Holter ECG / *Holter systems*

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta all'attività di direzione e coordinamento di Kiwa Italia Holding S.r.l.
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Tel +39.051.459.3.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwacermet.it

Rif. rapporto di audit/ *Ref. audit report:* 12-13-14-15/01/2021

Chief Operating Officer
Giampiero Belcredi

Firmato digitalmente da:BELCREDI GIAMPIERO
Data:24/05/2021 17:06:11

Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Reg. Numero / *Reg. Number*	MED 26032	Revisione / *Revision*	10
Primo rilascio / *First issue date*	2006-09-07	Valido da / *Valid from*	2021-05-24
Scadenza / *Valid until*	2024-05-26	Ultima modifica / *Last change date*	2021-05-24

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Carte di registrazione per apparecchiature elettromedicali / *Recording chart paper for medical devices*

Classe di rischio / *Risk class:*
I m - Limitatamente agli aspetti relativi ai requisiti metrologici / restricted to the aspects concerned the metrological requirements

Codice NANDO / *NANDO codes:*
MD 0104

Modello / Model:

Carte termiche prive di Bisfenoli / Phenol free chart paper

Codici / Codes:

CF αα xxx (/yyy) BF αα xxx (/yyy)

Tipologia / *Medical Devices:*
Dispositivi monouso per diagnostica polmonare / *Disposable devices for pulmonary test*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 0106

Modello / Model:

Boccagli / Mouthpieces

Codici / Codes:

TSxxxx (/yyyy); 910300

Modello / Model:

Boccagli con filtro antiparticolato / Mouthpieces with particulate filter

Codici / Codes:

TSFxxxx

Modello / Model:

Filtri B.V. (batterici - virali) / Bacterial-viral filters

Codici / Codes:

TSVBM xxx (/yyy)

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Chief Operating Officer
Giampiero Belcredi

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Data:24/05/2021 17:06:29

CE

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Notified Body nr. 0476

CERTIFICATE

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Scadenza / *Valid until*	2024-05-26	Ultima modifica / *Last change date*	2021-05-24

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Elettrocardiografi / *Electrocardiographs*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 1302

Modello / Model:

euro_ecg 3view; euro_ecg 6view; euro_ecg 12view;

Codici / Codes:

EP-LU30001 EP-LU30002 EP-LU30003

Tipologia / *Medical Devices:*
Elettrocardiografi di seconda generazione / *Electrocardiographs*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 1302

Modello / Model:

euro_ecg 301A; euro_ecg 301; euro_ecg 301B; euro_ecg 601A; euro_ecg 601; euro_ecg 601B; euro_ecg 1201A; euro_ecg 1201; euro_ecg 1201B

Codici / Codes:

EP-LU30111, EP-LU30101, EP-LU30121, EP-LU30112, EP-LU30102, EP-LU30122, EP-LU30113, EP-LU30103, EP-LU30123

Kiwa Cermet Italia S.p.A.
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E-mail: info@kiwacermet.it
www.kiwacermet.it

Chief Operating Officer
Giampiero Belcredi

Firmato digitalmente da:BELCREDI GIAMPIERO
Data:24/05/2021 17:06:47

CERMET

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Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Reg. Numero / *Reg. Number*	MED 26032	Revisione / *Revision*	10
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Scadenza / *Valid until*	2024-05-26	Ultima modifica / *Last change date*	2021-05-24

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Holter ECG / *Holter systems*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 1302

Modello / Model:

euro_holter 3view ; euro_holter 12view

Codici / Codes:

EP-LU20001 EP-LU20002 EP-LU20003 EP-LU20004

La lista completa dei codici, relativi ai modelli certificati, è disponibile presso Kiwa Cermet Italia./ *The complete list of the codes related to the certificated models is available at Kiwa Cermet Italia.* Il presente Certificato è soggetto al rispetto dei requisiti contrattuali di Kiwa Cermet Italia ed è valido solo per le tipologie di dispositivi sopra identificate soggette a sorveglianza/ *This Certificate is subject to Kiwa Cermet Italia regulations and it is valid only for the above mentioned Medical Devices that are subject to survey.* L'allegato tecnico è parte integrante del presente Certificato./ *The technical sheet is an integrating part of this Certificate.*

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Chief Operating Officer
Giampiero Belcredi

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Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Reg. Numeris	MED 26032	*Peržiūra/*	10
Pirmo suteikimo data	2006-09-07	*Galioja nuo/*	2021-05-24
Galioja iki/	2024-05-26	*Paskutinio pakeitimo data/*	2021-05-24

EB kokybės užtikrinimo sistemos

Patvirtiname, kad atliktų auditų pagrindu Organizacijos Gamybos kokybės užtikrinimo sistema:

LUMED S.r.l.

Operatyvinė būstinė:
Via Staffora, 18/9
20073 Opera, MI - Italija

Registruota būstinė
Via Vittor Pisani, 28
20124 Milanas, MI - Italija

Operatyvinė būstinė
Via Senio, 36/40
47121 Forlì, FC - Italija

Atitinka taikomus 93/42/EEB direktyvos su pakeitimais V priedo reikalavimus, kuriuos Italijoje perkėlė Dlgs. 1997/02/24 46 su pakeitimais dėl šių medicinos prietaisų:

Medicinos prietaisų įrašymo diagramų popierius
Vienkartiniai prietaisai plaučių tyrimui
Elektrokardiografija
Elektrokardiografai
Holter sistemos

Ref. audito ataskaita: 12-13-14-15/01/2021

Vyriausiasis veiklos vadovas
Giampiero Belcredi

Firmato digitalmente da:BELCREDI GIAMPIERO
Data:24/05/2021 17:06:11

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CERTIFICATE

Reg. Numeris	MED 26032	Peržiūra	10
Pirmo suteikimo data	2006-09-07	Galioja nuo	2021-05-24
Galioja iki	2024-05-26	*Paskutinio pakeitimo data*	2021-05-24

Prie sertifikato pridedamas techninis lapas

Medicinos prietaisų identifikavimas:

Medicinos prietaisas:

Medicinos prietaisų įrašymo diagramų popierius

Rizikos klasė:
tik su metrologiniais reikalavimais susijusiais aspektais

NANDO kodas:
MD 0104

Modelis:

Diagramos popierius be fenolio

Kodas:

CF αα xxx (/yyy) BF αα xxx (/yyy)

Medicinos prietaisas:

Vienkartiniai prietaisai plaučių tyrimui

Rizikos klasė:
II a

NANDO kodas:
MD 0106

Modelis:

Kandikliai

Kodai:

TSxxxx (/yyyy); 910300

Modelis:

Kandikliai su kietųjų dalelių filtru

Kodai:

TSFxxxx

Modelis:

Bakteriniai-virusiniai filtrai

Kodai:

TSVBM xxx (/yyy)

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Galioja iki	2024-05-26	*Paskutinio pakeitimo data*	2021-05-24

Prie sertifikato pridedamas techninis lapas

Medicinos prietaisų identifikavimas:

Mediciniai prietaisai:
Elektrokardiografai

Rizikos klasė:
II a

NANDO kodas:
MD 1302

Modelis:

euro_ecg 3view; euro_ecg 6view; euro_ecg 12view;

Kodai:

EP-LU30001 EP-LU30002 EP-LU30003

Medicinos prietaisai:
Elektrokardiografai

Rizikos klasė:
II a

NANDO kodas:
MD 1302

Modelis:

euro_ecg 301A; euro_ecg 301; euro_ecg 301B; euro_ecg 601A; euro_ecg 601; euro_ecg 601B; euro_ecg 1201A; euro_ecg 1201; euro_ecg 1201B

Kodai:

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Galioja iki	2024-05-26	*Paskutinio pakeitimo data*	2021-05-24

Prie sertifikato pridedamas techninis lapas

Medicinos prietaisų identifikavimas:

Medicinos prietaisai:
Holterio sistema

Rizikos klasė:
II a

NANDO kodai:
MD 1302

Modelis:

euro_holter 3view ; euro_holter 12view

Kodas:

EP-LU20001 EP-LU20002 EP-LU20003 EP-LU20004

Visą kodų, susijusių su sertifikuotais modeliais, sąrašą rasite Kiwa Cermet Italia.Šiam sertifikatui taikomi Kiwa Cermet Italia reglamentai ir jis galioja tik pirmiau minėtiems medicinos prietaisams, kuriems taikomas tyrimas. Techninis lapas yra sudedamoji šio sertifikato dalis.

Kiwa Cermet Italia S.p.A.
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Vyriausiasis veiklos vadovas
Giampiero Belcredi

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