CE SERTIFIKATAS – PILNOS KOKYBĖS UŽTIKRINIMO SISTEMA

Sertifikato Nr:	Projekto Nr:	Galioja iki:
11168-2017-CE-IND-NA-PS Rev. 1.0	PRJC-503753-2014-MSL-IND	2024 Gegužės 27

Šiuo setifikatu patvirtinama, kad kokybės valdymo sistema:

Harsoria Healthcare Pvt. Ltd.
110-111, Udyog Vihar Phase-4, Gurugram – 122015, Haryana, Indija

kūrimui, gamybai ir galutinei apžiūrai

Sterilių Medicinos Prietaisų infuzijos ir transfuzijos terapijai

įvertinta remiantis
atitikties įvertinimo procedūra aprašyta Straipsnyje 11.3.a ir Medicinos prietaisų 93/42/EEC direktyvos Priede II (išskyrus skyrių 4), atitinka

Skaitykite kitame puslapyje

Vieta ir laikas:
Hovik, 2020-07-14

DNV GL NEMKO PRESAFE AS
Notifikuota įstaiga Nr.: 2460

/parašas/
Palani Damodharan

CE SERTIFIKATAS – PILNOS KOKYBĖS UŽTIKRINIMO SISTEMA

Sertifikato Nr:	Projekto Nr:	Galioja iki:
11168-2017-CE-IND-NA-PS Rev. 1.0	PRJC-503753-2014-MSL-IND	2024 Gegužės 27

Teisingumas

1993-06-14 93/42/EEC direktyvos taikymas, Norvegijos sveikatos ir priežiūros tarnybos ministerijos pasirinkta kaip „Forskrift Medisinsk Utstyr“.

Sertifikato išklotinė

Peržiūra	Aprašymas	Išleidimo data
0.0	**Pakeičia DNVGL (NB 0434) Sertifikatą Nr.: 5262-2014-CE-IND-NA 0.0 po notifikuotos įstaigos funkcijų pakeitimo į DNV GL Nemko Presafe AS (NB 2460)**	**2017-10-12**
1.0	Persertifikavimas	2020-07-14

Šiuo sertifikatu apsaugoti gaminiai

Gaminio aprašymas	Gaminio pavadinimas	Klasė
Intraveninė kaniulė su kateteriu, su arba be injekcijos lizdo, su arba be sparnelių	Dydžiai 12G, 13G, 14G, 16G, 17G, 18G, 20G, 22G, 24G, 26G	IIa
Saugi Intraveninė kaniulė su kateteriu, su arba be injekcijos lizdo, su arba be sparnelių	Dydžiai: 14G, 16G, 17G, 18G, 20G, 22G, 24G, 26G	IIa
Arterinių veninių adatų rinkinys	Dydžiai: 14G, 15G, 16G, 17G, 18G	IIa
3-jų krypčių kranelis su/be prailginimo linijų	Ilgis 5cm-300cm	IIa
Prailginimo linija	Ilgis 5cm-300cm	IIa
Dozatorius		IIa
Kamštelis		IIa
Combi Luer Lock kamštelis		IIa
Luer kamštelis		IIa

Pilnas prietaisų sąrašas pateikiamas Notifikuotos įstaigos.

Sertifikato patvirtintos vietos

Vieta	Adresas
Harsoria Healthcare Pvt. Ltd.	110-111, Udyog Vihar phase-4, Gurugram – 122 015, Haryana, Indija

Europos sąjungos įgaliotinis

CE SERTIFIKATAS – PILNOS KOKYBĖS UŽTIKRINIMO SISTEMA

Sertifikato Nr:	Projekto Nr:	Galioja iki:
11168-2017-CE-IND-NA-PS Rev. 1.0	PRJC-503753-2014-MSL-IND	2024 Gegužės 27

Įmonės pavadinimas	**Adresas**
Mdi Europa GmhH	Langenhagener Str. 71, 30855 Langenhagen, Vokietija

CE SERTIFIKATAS – PILNOS KOKYBĖS UŽTIKRINIMO SISTEMA

Sertifikato Nr:	Projekto Nr:	Galioja iki:
11168-2017-CE-IND-NA-PS Rev. 1.0	PRJC-503753-2014-MSL-IND	2024 Gegužės 27

Sąlygos ir terminai:

Sertifikatui galioja šios sąlygos ir terminai:

- Remiantis 85/374/EEC direktyva, bet kuris gamintojas (tiksliau ieškokite 2001/95/EC) yra atsakingas už prastos gaminio kokybės sukeltą žalą.
- Sertifikatas galioja tik anksčiau išvardintiems gaminiams.
- Gamintojas privalo įvykdyti pareigas, susijusias su kokybės sistema bei laikytis jų, užtikrindamas jų efektyvumą ir tinkamumą.
- Gamintojas privalo informuoti vietinę Presafe įstaigą apie bet kokius kokybės sistemos atnaujinimus; Presafe įvertina pasikeitimus ir nusprendžia ar sertifikatas vis dar gali būti laikomas galiojančiu.
- Siekiant įvertinti ar gamintojas taiko kokybės sistemą, atliekamos periodinės apžiūros.

Šioms sąlygoms esant sertifikatas laikomas negaliojančiu:

- Esant kokybės sistemos pakitimams, kurie įtakoja gamybą.
- Periodininės apžiūros nėra atliekamos nustatytu terminu.

Atitikties deklaracija ir gaminio ženklinimas

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 107353 0004 Rev. 00

Manufacturer:

Harsoria Healthcare Pvt. Ltd
110-111 Udyog Vihar Phase-4
Gurgaon, Haryana 122015
INDIA

SRN Manufacturer - IN-MF-000018349

Authorized Representative:

Mdi Europa GmbH
Langenhagener Str. 71, 30855 Langenhagen, GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s). The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples. All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G10 107353 0004 Rev. 00

Report No.: TPS0882
Valid from: 2024-03-13
Valid until: 2029-03-12

Issue date: 2024-03-13

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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BS-MDR-099

TÜV SÜD Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class IIa and Class IIb Devices)

No. G10 107353 0004 Rev. 00

Classification:	Class IIa
Device Group:	A01020302 - CUTANEOUS BIOPSY PUNCHES, SINGLE-USE
Intended Purpose:	-

Classification:	Class IIa
Device Group:	A010401 - ARTERIOVENOUS FISTULA NEEDLES
Intended Purpose:	-

Classification:	Class IIa
Device Group:	A030104 - FLOW REGULATORS
Intended Purpose:	-

Classification:	Class IIa
Device Group:	A03020101 - LOW PRESSURE EXTENSION LINES
Intended Purpose:	-

Classification:	Class IIa
Device Group:	A03020102 - HIGH PRESSURE EXTENSION LINES
Intended Purpose:	-

Classification:	Class IIa
Device Group:	A03010101 - INFUSION CONTROLLERS WITH OR W/O AIR INLET
Intended Purpose:	-

Classification:	Class IIa
Device Group:	A0703 - STOPCOCKS
Intended Purpose:	-

Classification:	Class IIa
Device Group:	A070501 - CAPS OR OBTURATORS, NON-PERFORABLE
Intended Purpose:	-

Classification:	Class IIa
Device Group:	A070502 - CAPS OR OBTURATORS, PERFORABLE
Intended Purpose:	-

Classification:	Class IIa
Device Group:	C0101010101 - PERIPHERAL I.V. CATHETERS, W/O SAFETY

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TÜV SÜD
Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class IIa and Class IIb Devices)

No. G10 107353 0004 Rev. 00

	SYSTEMS, WITH INJECTION VALVES
Intended Purpose:	-
Classification:	Class IIa
Device Group:	C0101010102 - PERIPHERAL I.V. CATHETERS, W/O SAFETY SYSTEMS, W/O INJECTION VALVES
Intended Purpose:	-
Classification:	Class IIa
Device Group:	C0101010201 - PERIPHERAL I.V. CATHETERS, WITH SAFETY SYSTEMS, WITH INJECTION VALVES
Intended Purpose:	-
Classification:	Class IIa
Device Group:	C0101010202 - PERIPHERAL I.V. CATHETERS, WITH SAFETY SYSTEMS, W/O INJECTION VALVES
Intended Purpose:	-
Classification:	Class IIa
Device Group:	F900201 - TEMPORARY HEMODIALYSIS CATHETERS AND KITS
Intended Purpose:	-
Classification:	Class IIa
Device Group:	R01030101 - ENDOTRACHEAL TUBES, CUFFLESS, NOT REINFORCED
Intended Purpose:	-
Classification:	Class IIa
Device Group:	R01030201 - ENDOTRACHEAL TUBES, CUFFED, NOT REINFORCED
Intended Purpose:	-
Classification:	Class IIa
Device Group:	R01030202 - ENDOTRACHEAL TUBES, CUFFED, REINFORCED
Intended Purpose:	-
Classification:	Class IIa
Device Group:	R03010301 - AEROSOL THERAPY MASKS
Intended Purpose:	-

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TÜV SÜD Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 107353 0004 Rev. 00

Classification:	Class IIa
Device Group:	R9004 - PLEURAL TALCAGE DEVICES
Intended Purpose:	-

Classification:	Class IIa
Device Group:	W0501010180 - VENOUS OR ARTERIOUS BLOOD COLLECTION DEVICES - ACCESSORIES
Intended Purpose:	-

The validity of this certificate depends on conditions and/or is limited to the following:	-

Revision History:

Rev.	Dated	Report	Description
00	2024-03-13	TPS0882	Initial issuance

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EC CERTIFICATION

QUALITY ASSURANCE CERTIFICATE

EU Regulation 2017/745 for Medical Devices, Annex XI Part A

We hereby declare that a conformity assessment based on a production quality assurance system and technical documentation (excluding type-examination) has been carried out following the requirements of EU Regulation 2017/745 for Medical Devices.

We certify that the documentation conforms to the relevant provisions of the aforementioned regulation, and the result entitles the organization to use the CE 2862 marking on the products listed below.

Certificate Number:
28620139578-01

Initial Certification Date:
12 January 2023

Date of Certification Decision:
3 February 2023

Certificate Issue Date:
3 February 2023

Certificate Expiry Date:
11 January 2028

Henan Tuoren Medical Device Co., Ltd

Weiyuan Industrial Zone, Menggang, Changyuan, 453400 Henan Province, P. R. China

Manufacturer SRN: CN-MF-000013924

Authorised Representative Name
MedNet EC-REP GmbH
Address at Borkstraße, 10 48163 Münster

Scope:

- Respiratory airway devices
- Non-active devices for administration, channelling and removal of substances

Brian Mather
Certification Authority, MDR
Intertek Medical Notified Body AB,
Torshamnsgatan 43,
Box 1103, SE-164 22 Kista, Sweden

Intertek Medical Notified Body AB is a Notified Body in accordance with the requirements set out in EU Regulation 2017/745 on medical devices, with the identification number 2862.

PRODUCT LIST FOR CERTIFICATE

See attached Product List

EXAMINATION AND TESTS PERFORMED

Technical Assessment Report Reference	**TD00150-01 Henan Tuoren Medical Device Co., Ltd I.V. Cannula**
	TD00150-02 Henan Tuoren Medical Device Co., Ltd Tracheostomy Tube
Last Audit report reference	**Stage 1 audit ACTY-2022-579507**
	Stage 2 audit ACTY-2022-591573

CONDITIONS FOR OR LIMITATIONS TO VALIDITY OF CERTIFICATE

None

CERTIFICATE HISTORY

PRECEDING CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES
28620139578	12 January 2023	Initial certificate

Certificate Number:
28620139578-01

Initial Certification Date:
12 January 2023

Date of Certification Decision:
3 February 2023

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3 February 2023

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11 January 2028

Brian Mather
Certification Authority, MDR
Intertek Medical Notified Body AB,
Torshamnsgatan 43,
Box 1103, SE-164 22 Kista, Sweden

Intertek Medical Notified Body AB is a Notified Body in accordance with the requirements set out in EU Regulation 2017/745 on medical devices, with the identification number 2862.

PRODUCT LIST FOR CERTIFICATE

Issued to: Henan Tuoren Medical Device Co., Ltd.

Certificate number: 28620139578-01

Certificate valid from: 2023-02-03

Product List Issue Date:
24 February 2023

Product	Classification and EMDN	Intended use[1]	Date Added
Non-active devices for administration, channelling and removal of substances			
Basic UDI-DI: 693811931294HW			
IVB010X(X:18,20,22,24) - I.V. Cannula X: Specification (18:18G,20:20G,22:22G,24:24G)	Class IIa		2023-01-12
IVB110X(X:18,20,22,24) - I.V. Cannula X: Specification (18:18G,20:20G,22:22G,24:24G)	Class IIa		2023-01-12
IVI011X(X:18,20,22,24) - I.V. Cannula X: Specification (18:18G,20:20G,22:22G,24:24G)	Class IIa		2023-01-12
IVS010X(X:18,20,22,24) - I.V. Cannula X: Specification (18:18G,20:20G,22:22G,24:24G)	Class IIa		2023-01-12
IVY010X(X:18,20,22,24,26) - I.V. Cannula X: Specification (18:18G,20:20G,22:22G,24:24G,26:26G)	Class IIa		2023-01-12
IVY011X(X:18,20,22,24,26) - I.V. Cannula X: Specification (18:18G,20:20G,22:22G,24:24G,26:26G)	Class IIa		2023-01-12
IVY110X(X:18,20,22,24,26) - I.V. Cannula X: Specification (18:18G,20:20G,22:22G,24:24G,26:26G)	Class IIa		2023-01-12
IVY111X(X:18,20,22,24,26) - I.V. Cannula X: Specification (18:18G,20:20G,22:22G,24:24G,26:26G)	Class IIa		2023-01-12
Basic UDI-DI: 693811931295HY			

[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

Product	Classification and EMDN	Intended use[1]	Date Added
SCCDAX(X:5, 6, 7, 8,10, 12, 14, 16) - Closed Suction Catheter X: Specification(5:5Fr, 6:6Fr, 7:7Fr,8: 8Fr, 10:10Fr, 12:12Fr, 14:14Fr, 16:16Fr)	Class IIa		2023-01-12
SCCDPX(X:5, 6, 7, 8,10, 12, 14, 16) - Closed Suction Catheter X: Specification(5:5Fr, 6:6Fr, 7:7Fr,8: 8Fr, 10:10Fr, 12:12Fr, 14:14Fr, 16:16Fr)	Class IIa		2023-01-12
SCCDWX(X:5, 6, 7, 8,10, 12, 14, 16) - Closed Suction Catheter X: Specification(5:5Fr, 6:6Fr, 7:7Fr,8: 8Fr, 10:10Fr, 12:12Fr, 14:14Fr, 16:16Fr)	Class IIa		2023-01-12
SCCEAX(X:5, 6, 7, 8,10, 12, 14, 16) - Closed Suction Catheter X: Specification(5:5Fr, 6:6Fr, 7:7Fr,8: 8Fr, 10:10Fr, 12:12Fr, 14:14Fr, 16:16Fr)	Class IIa		2023-01-12
SCCEPX(X:5, 6, 7, 8,10, 12, 14, 16) - Closed Suction Catheter X: Specification(5:5Fr, 6:6Fr, 7:7Fr,8: 8Fr, 10:10Fr, 12:12Fr, 14:14Fr, 16:16Fr)	Class IIa		2023-01-12
SCCEWX(X:5, 6, 7, 8,10, 12, 14, 16) - Closed Suction Catheter X: Specification(5:5Fr, 6:6Fr, 7:7Fr,8: 8Fr, 10:10Fr, 12:12Fr, 14:14Fr, 16:16Fr)	Class IIa		2023-01-12
SCCPAX(X:5, 6, 7, 8) - Closed Suction Catheter X: Specification(5:5Fr, 6:6Fr, 7:7Fr,8: 8Fr)	Class IIa		2023-01-12
SCCPPX(X: 5, 6, 7, 8) - Closed Suction Catheter X: Specification(5:5Fr, 6:6Fr, 7:7Fr,8: 8Fr)	Class IIa		2023-01-12
SCCPWX(X:5, 6, 7, 8) - Closed Suction Catheter X: Specification(5:5Fr, 6:6Fr, 7:7Fr,8: 8Fr)	Class IIa		2023-01-12
SCCRAX(X:5, 6, 7, 8,10, 12, 14, 16) - Closed Suction Catheter X: Specification(5:5Fr, 6:6Fr, 7:7Fr,8: 8Fr, 10:10Fr, 12:12Fr, 14:14Fr, 16:16Fr)	Class IIa		2023-01-12
SCCRPX(X:5, 6, 7, 8,10, 12, 14, 16) - Closed Suction Catheter X: Specification(5:5Fr, 6:6Fr, 7:7Fr,8: 8Fr, 10:10Fr, 12:12Fr, 14:14Fr, 16:16Fr)	Class IIa		2023-01-12
SCCRWX(X:5, 6, 7, 8,10, 12, 14, 16) - Closed Suction Catheter X: Specification(5:5Fr, 6:6Fr, 7:7Fr,8: 8Fr, 10:10Fr, 12:12Fr, 14:14Fr, 16:16Fr)	Class IIa		2023-01-12

[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

Certificate number: 28620139578-01
Product list issue date: 24 February 2023

Product	Classification and EMDN	Intended use[1]	Date Added
SCCVAX(X:5, 6, 7, 8,10, 12, 14, 16) - Closed Suction Catheter X: Specification(5:5Fr, 6:6Fr, 7:7Fr,8: 8Fr, 10:10Fr, 12:12Fr, 14:14Fr, 16:16Fr)	Class IIa		2023-01-12
SCCVPX(X:5, 6, 7, 8,10, 12, 14, 16) - Closed Suction Catheter X: Specification(5:5Fr, 6:6Fr, 7:7Fr,8: 8Fr, 10:10Fr, 12:12Fr, 14:14Fr, 16:16Fr)	Class IIa		2023-01-12
SCCVWX(X:5, 6, 7, 8,10, 12, 14, 16) - Closed Suction Catheter X: Specification(5:5Fr, 6:6Fr, 7:7Fr,8: 8Fr, 10:10Fr, 12:12Fr, 14:14Fr, 16:16Fr)	Class IIa		2023-01-12
Respiratory airway devices *Basic UDI-DI: 6938119312961J2*			
AET0X(X:065,070,075) - Endotracheal Tube X: Specification (065:6.5,070:7.0,075:7.5)	Class IIa		2023-01-12
ET0X(X:020,025,030,035,040,045,050, 055,060,065,070,075,080,085,090,09 5,100) - Endotracheal Tube X:Specification(020:2.0,025:2.5,030:3. 0,035:3.5,040:4.0,045:4.5,050:5.0,055: 5,060:6.0,065:6.5,070:7.0,075:7.5,08 0:8.0,085:8.5,090:9.0,095:9.5,100:10.0)	Class IIa		2023-01-12
ET1X(X:020,025,030,035,040,045,050, 055,060,065,070,075,080,085,090,09 5,100) - Endotracheal Tube X:Specification(020:2.0,025:2.5,030:3. 0,035:3.5,040:4.0,045:4.5,050:5.0,055: 5,060:6.0,065:6.5,070:7.0,075:7.5,08 0:8.0,085:8.5,090:9.0,095:9.5,100:10.0)	Class IIa		2023-01-12
ETT0X(X:025,030,035,040,045,050,05 5,060,065,070,075,080) - Endotracheal Tube X:Specification(025:2.5,030:3.0,035:3. 5,040:4.0,045:4.5,050:5.0,055:5.5,060: 6.0,065:6.5,070:7.0,075:7.5,080:8.0)	Class IIa		2023-01-12
IET0X(X:060,065,070,075,080) - Endotracheal Tube X: Specification (060:6.0,065:6.5,070:7.0,075:7.5,080: 8.0)	Class IIa		2023-01-12

[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

Certificate number: 28620139578-01
Product list issue date: 24 February 2023

Product	Classification and EMDN	Intended use[1]	Date Added
LET0X(X:025,030,035,040,045,050,055,060,065,070,075,080,085,090,095,100} Endotracheal Tube X:Specification(025:2.5,030:3.0,035:3.5,040:4.0,045:4.5,050:5.0,055:5.5,060:6.0,065:6.5,070:7.0,075:7.5,080:8.0,085:8.5,090:9.0,095:9.5,100:10.0)	Class IIa		2023-01-12
LNET0X(X:025,030,035,040,045,050,055,060,065,070,075,080,085,090) - Endotracheal Tube X:Specification(025:2.5,030:3.0,035:3.5,040:4.0,045:4.5,050:5.0,055:5.5,060:6.0,065:6.5,070:7.0,075:7.5,080:8.0,085:8.5,090:9.0)	Class IIa		2023-01-12
LOET0X(X:025,030,035,040,045,050,055,060,065,070,075,080,085,090) - Endotracheal Tube X:Specification(025:2.5,030:3.0,035:3.5,040:4.0,045:4.5,050:5.0,055:5.5,060:6.0,065:6.5,070:7.0,075:7.5,080:8.0,085:8.5,090:9.0)	Class IIa		2023-01-12
NET0X(X:025,030,035,040,045,050,055,060,065,070,075,080,085,090,095,100) - Endotracheal Tube X:Specification(025:2.5,030:3.0,035:3.5,040:4.0,045:4.5,050:5.0,055:5.5,060:6.0,065:6.5,070:7.0,075:7.5,080:8.0,085:8.5,090:9.0,095:9.5,100:10.0)	Class IIa		2023-01-12
NET1X(X:025,030,035,040,045,050,055,060,065,070,075,080,085,090,095,100) - Endotracheal Tube X:Specification(025:2.5,030:3.0,035:3.5,040:4.0,045:4.5,050:5.0,055:5.5,060:6.0,065:6.5,070:7.0,075:7.5,080:8.0,085:8.5,090:9.0,095:9.5,100:10.0)	Class IIa		2023-01-12
OET0X(X:025,030,035,040,045,050,055,060,065,070,075,080,085,090,095,100) - Endotracheal Tube X:Specification(025:2.5,030:3.0,035:3.5,040:4.0,045:4.5,050:5.0,055:5.5,060:6.0,065:6.5,070:7.0,075:7.5,080:8.0,085:8.5,090:9.0,095:9.5,100:10.0)	Class IIa		2023-01-12
OET1X(X:025,030,035,040,045,050,055,060,065,070,075,080,085,090,095,100) - Endotracheal Tube X:Specification(025:2.5,030:3.0,035:3.5,040:4.0,045:4.5,050:5.0,055:5.5,060:6.0,065:6.5,070:7.0,075:7.5,080:8.0,085:8.5,090:9.0,095:9.5,100:10.0)	Class IIa		2023-01-12

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SET0X(X:060,065,070,075,080,085) - Endotracheal Tube X: Specification (060:6.0,065:6.5,070:7.0,075:7.5,080:8.0,085:8.5)	Class IIa		2023-01-12
SIET0X(X:065,070,075,080) - Endotracheal Tube X： Specification （065:6.5,070:7.0,075:7.5,080:8.0）	Class IIa		2023-01-12
STET0X(X:025,030,035,040,045,050,055,060,065,070,075,080,085,090,095,100) - Endotracheal Tube X:Specification(025:2.5,030:3.0,035:3.5,040:4.0,045:4.5,050:5.0,055:5.5,060:6.0,065:6.5,070:7.0,075:7.5,080:8.0,085:8.5,090:9.0,095:9.5,100:10.0)	Class IIa		2023-01-12
STNET0X(X:025,030,035,040,045,050,055,060,065,070,075,080,085,090,095,100) - Endotracheal Tube X:Specification(025:2.5,030:3.0,035:3.5,040:4.0,045:4.5,050:5.0,055:5.5,060:6.0,065:6.5,070:7.0,075:7.5,080:8.0,085:8.5,090:9.0,095:9.5,100:10.0)	Class IIa		2023-01-12
STOET0X(X:025,030,035,040,045,050,055,060,065,070,075,080,085,090,095,100) - Endotracheal Tube X:Specification(025:2.5,030:3.0,035:3.5,040:4.0,045:4.5,050:5.0,055:5.5,060:6.0,065:6.5,070:7.0,075:7.5,080:8.0,085:8.5,090:9.0,095:9.5,100:10.0)	Class IIa		2023-01-12
Basic UDI-DI: 69381193129 7J4			
ARET0X(X: 060, 065, 070, 075) - Reinforced Endotracheal Tube X: Specification(060: 6.0mm, 065: 6.5mm, 070: 7.0mm, 075: 7.5mm)	Class IIa		2023-01-12
BRET0X(X: 030, 035, 040, 045, 050, 055, 060, 065, 070, 075, 080) - Reinforced Endotracheal Tube X: Specification(030: 3.0mm, 035: 3.5mm, 040: 4.0mm, 045: 4.5mm, 050: 5.0mm, 055: 5.5mm, 060: 6.0mm, 065: 6.5mm, 070: 7.0mm, 075: 7.5mm, 080: 8.0mm)	Class IIa		2023-01-12

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Product	Classification and EMDN	Intended use[1]	Date Added
BRETE0X(X: 030, 035, 040, 045, 050, 055, 060, 065, 070, 075, 080) - Reinforced Endotracheal Tube X: Specification(030: 3.0mm, 035: 3.5mm, 040: 4.0mm, 045: 4.5mm, 050: 5.0mm, 055: 5.5mm, 060: 6.0mm, 065: 6.5mm, 070: 7.0mm, 075: 7.5mm, 080: 8.0mm)	Class IIa		2023-01-12
LNRET0X(X: 025, 030, 035, 040, 045, 050, 055, 060, 065, 070, 075, 080, 085, 090) - Reinforced Endotracheal Tube X： Specification(025: 2.5mm, 030: 3.0mm, 035: 3.5mm, 040: 4.0mm, 045: 4.5mm, 050: 5.0mm, 055: 5.5mm, 060: 6.0mm, 065: 6.5mm, 070: 7.0mm, 075: 7.5mm, 080: 8.0mm, 085: 8.5mm, 090: 9.0mm)	Class IIa		2023-01-12
LORET0X(X: 025, 030, 035, 040, 045, 050, 055, 060, 065, 070, 075, 080, 085, 090) - Reinforced Endotracheal Tube X: Specification(025: 2.5mm, 030: 3.0mm, 035: 3.5mm, 040: 4.0mm, 045: 4.5mm, 050: 5.0mm, 055: 5.5mm, 060: 6.0mm, 065: 6.5mm, 070: 7.0mm, 075: 7.5mm, 080: 8.0mm, 085: 8.5mm, 090: 9.0mm)	Class IIa		2023-01-12
LRET0X(X: 025, 030, 035, 040, 045, 050, 055, 060, 065, 070, 075, 080, 085, 090, 095, 100) - Reinforced Endotracheal Tube X: Specification(025: 2.5mm, 030: 3.0mm, 035: 3.5mm, 040: 4.0mm, 045: 4.5mm, 050: 5.0mm, 055: 5.5mm, 060: 6.0mm, 065: 6.5mm, 070: 7.0mm, 075: 7.5mm, 080: 8.0mm, 085: 8.5mm, 090: 9.0mm, 095: 9.5mm, 100: 10.0mm)	Class IIa		2023-01-12
NRET0X(X: 025, 030, 035, 040, 045, 050, 055, 060, 065, 070, 075, 080, 085, 090， 095, 100) - Reinforced Endotracheal Tube X: Specification(025: 2.5mm, 030: 3.0mm, 035: 3.5mm, 040: 4.0mm, 045: 4.5mm, 050: 5.0mm, 055: 5.5mm, 060: 6.0mm, 065: 6.5mm, 070: 7.0mm, 075: 7.5mm, 080: 8.0mm, 085: 8.5mm, 090: 9.0mm, 095: 9.5mm, 100: 10.0mm)	Class IIa		2023-01-12

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NRET1X(X: 025, 030, 035, 040, 045, 050, 055, 060, 065, 070, 075, 080, 085, 090, 095, 100) - Reinforced Endotracheal Tube X: Specification(025: 2.5mm, 030: 3.0mm, 035: 3.5mm, 040: 4.0mm, 045: 4.5mm, 050: 5.0mm, 055: 5.5mm, 060: 6.0mm, 065: 6.5mm, 070: 7.0mm, 075: 7.5mm, 080: 8.0mm, 085: 8.5mm, 090: 9.0mm, 095: 9.5mm, 100: 10.0mm)	Class IIa		2023-01-12
ORET0X(X: 025, 030, 035, 040, 045, 050, 055, 060, 065, 070, 075, 080, 085, 090, 095, 100) - Reinforced Endotracheal Tube X: Specification(025: 2.5mm, 030: 3.0mm, 035: 3.5mm, 040: 4.0mm, 045: 4.5mm, 050: 5.0mm, 055: 5.5mm, 060: 6.0mm, 065: 6.5mm, 070: 7.0mm, 075: 7.5mm, 080: 8.0mm, 085: 8.5mm, 090: 9.0mm, 095: 9.5mm, 100: 10.0mm)	Class IIa		2023-01-12
ORET1X(X: 025, 030, 035, 040, 045, 050, 055, 060, 065, 070, 075, 080, 085, 090, 095, 100) - Reinforced Endotracheal Tube X: Specification(025: 2.5mm, 030: 3.0mm, 035: 3.5mm, 040: 4.0mm, 045: 4.5mm, 050: 5.0mm, 055: 5.5mm, 060: 6.0mm, 065: 6.5mm, 070: 7.0mm, 075: 7.5mm, 080: 8.0mm, 085: 8.5mm, 090: 9.0mm, 095: 9.5mm, 100: 10.0mm)	Class IIa		2023-01-12
RET0X(X: 025, 030, 035, 040, 045, 050, 055, 060, 065, 070, 075, 080, 085, 090, 095, 100) - Reinforced Endotracheal Tube X: Specification(025: 2.5mm, 030: 3.0mm, 035: 3.5mm, 040: 4.0mm, 045: 4.5mm, 050: 5.0mm, 055: 5.5mm, 060: 6.0mm, 065: 6.5mm, 070: 7.0mm, 075: 7.5mm, 080: 8.0mm, 085: 8.5mm, 090: 9.0mm, 095: 9.5mm, 100: 10.0mm)	Class IIa		2023-01-12
RET1X(X: 025, 030, 035, 040, 045, 050, 055, 060, 065, 070, 075, 080, 085, 090, 095, 100) - Reinforced Endotracheal Tube X: Specification(025: 2.5mm, 030: 3.0mm, 035: 3.5mm, 040: 4.0mm, 045: 4.5mm, 050: 5.0mm, 055: 5.5mm, 060: 6.0mm, 065: 6.5mm, 070: 7.0mm, 075: 7.5mm, 080: 8.0mm, 085: 8.5mm, 090: 9.0mm, 095: 9.5mm, 100: 10.0mm)	Class IIa		2023-01-12

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Product	Classification and EMDN	Intended use[1]	Date Added
RETS0X(X: 025, 030, 035, 040, 045, 050, 055, 060, 065, 070, 075, 080, 085, 090, 095, 100) - Reinforced Endotracheal Tube X: Specification(025: 2.5mm, 030: 3.0mm, 035: 3.5mm, 040: 4.0mm, 045: 4.5mm, 050: 5.0mm, 055: 5.5mm, 060: 6.0mm, 065: 6.5mm, 070: 7.0mm, 075: 7.5mm, 080: 8.0mm, 085: 8.5mm, 090: 9.0mm, 095: 9.5mm, 100: 10.0mm)	Class IIa		2023-01-12
RETT0X(X: 025, 030, 035, 040, 045, 050, 055, 060, 065, 070, 075, 080) - Reinforced Endotracheal Tube X: Specification(025: 2.5mm, 030: 3.0mm, 035: 3.5mm, 040: 4.0mm, 045: 4.5mm, 050: 5.0mm, 055: 5.5mm, 060: 6.0mm, 065: 6.5mm, 070: 7.0mm, 075: 7.5mm, 080: 8.0mm)	Class IIa		2023-01-12
SRET0X(X: 060, 065, 070, 075, 080) - Reinforced Endotracheal Tube X: Specification(060: 6.0mm, 065: 6.5mm, 070: 7.0mm, 075: 7.5mm, 080: 8.0mm)	Class IIa		2023-01-12
Basic UDI-DI: 6938119312981J6			
DENLX(X: 026, 028, 031, 032, 033, 035, 037, 039, 041) - Endobronchial Tube X: Specification (026:Fr26, 028:Fr28, 031:Fr31, 032:Fr32, 033:Fr33, 035:Fr35, 037:Fr37, 039:Fr39, 041:Fr41)	Class IIa		2023-01-12
DENRX(X: 026, 028, 031, 032, 033, 035, 037, 039, 041) - Endobronchial Tube X: Specification (026:Fr26, 028:Fr28, 031:Fr31, 032:Fr32, 033:Fr33, 035:Fr35, 037:Fr37, 039:Fr39, 041:Fr41)	Class IIa		2023-01-12
Basic UDI-DI: 6938119312991J8			
ITF0X(X:050, 060, 065, 070, 075, 080) - Tracheostomy Tube X: 050: 5.0mm, 060: 6.0mm, 065: 6.5mm, 070: 7.0mm, 075: 7.5mm, 080: 8.0mm	Class IIa		2023-01-12
ITN0X(X:050, 060, 065, 070, 075, 080) - Tracheostomy Tube X: 050: 5.0mm, 060: 6.0mm, 065: 6.5mm, 070: 7.0mm, 075: 7.5mm, 080: 8.0mm	Class IIa		2023-01-12

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ITS0X(X:050, 060, 065, 070, 075, 080) - Tracheostomy Tube X: 050: 5.0mm, 060: 6.0mm, 065: 6.5mm, 070: 7.0mm, 075: 7.5mm, 080: 8.0mm	Class IIa		2023-01-12
PDTY0X(X: 070, 075, 080) - Tracheostomy Tube X: 070: 7.0mm, 075: 7.5mm, 080: 8.0mm	Class IIa		2023-01-12
PDTY1X(X: 070, 075, 080) - Tracheostomy Tube X: 070: 7.0mm, 075: 7.5mm, 080: 8.0mm	Class IIa		2023-01-12
STY0X(X: 060, 065, 070, 075, 080, 085) - Tracheostomy Tube X: 060: 6.0mm, 065: 6.5mm, 070: 7.0mm, 075: 7.5mm, 080: 8.0mm, 085: 8.5mm	Class IIa		2023-01-12
TYD0X(X: 070, 075, 080) - Tracheostomy Tube X: 070: 7.0mm, 075: 7.5mm, 080: 8.0mm	Class IIa		2023-01-12
TYN0X(X: 025, 030, 035, 040, 045, 050, 055, 060, 065, 070, 075, 080, 085, 090, 095, 100) - Tracheostomy Tube X: 025: 2.5mm, 030: 3.0mm, 035: 3.5mm, 040: 4.0mm, 045: 4.5mm, 050: 5.0mm, 055: 5.5mm, 060: 6.0mm, 065: 6.5mm, 070: 7.0mm, 075: 7.5mm, 080: 8.0mm, 085: 8.5mm, 090: 9.0mm, 095: 9.5mm, 100: 10.0mm	Class IIa		2023-01-12
TYN1X(X: 025, 030, 035, 040, 045, 050, 055, 060, 065, 070, 075, 080, 085, 090, 095, 100) - Tracheostomy Tube X: 025: 2.5mm, 030: 3.0mm, 035: 3.5mm, 040: 4.0mm, 045: 4.5mm, 050: 5.0mm, 055: 5.5mm, 060: 6.0mm, 065: 6.5mm, 070: 7.0mm, 075: 7.5mm, 080: 8.0mm, 085: 8.5mm, 090: 9.0mm, 095: 9.5mm, 100: 10.0mm	Class IIa		2023-01-12
TYR0X(X: 025, 030, 035, 040, 045, 050, 055, 060, 065, 070, 075, 080, 085, 090, 095, 100) - Tracheostomy Tube X: 025: 2.5mm, 030: 3.0mm, 035: 3.5mm, 040: 4.0mm, 045: 4.5mm, 050: 5.0mm, 055: 5.5mm, 060: 6.0mm, 065: 6.5mm, 070: 7.0mm, 075: 7.5mm, 080: 8.0mm, 085: 8.5mm, 090: 9.0mm, 095: 9.5mm, 100: 10.0mm	Class IIa		2023-01-12

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TYR1X(X: 025, 030, 035, 040, 045, 050, 055, 060, 065, 070, 075, 080, 085, 090, 095, 100) - Tracheostomy Tube X: 025: 2.5mm, 030: 3.0mm, 035: 3.5mm, 040: 4.0mm, 045: 4.5mm, 050: 5.0mm, 055: 5.5mm, 060: 6.0mm, 065: 6.5mm, 070: 7.0mm, 075: 7.5mm, 080: 8.0mm, 085: 8.5mm, 090: 9.0mm, 095: 9.5mm, 100: 10.0mm	Class IIa		2023-01-12
Basic UDI-DI: 693811931300GY			
LMA1X(X:10,15,20,25,30,40,50) - Laryngeal Mask Airway X: Specification (10:1.0,15:1.5,20:2.0,25:2.5,30:3.0,40:4.0,50:5.0)	Class IIa		2023-01-12
LMA2X(X:10,15,20,25,30,40,50) - Laryngeal Mask Airway X: Specification (10:1.0,15:1.5,20:2.0,25:2.5,30:3.0,40:4.0,50:5.0)	Class IIa		2023-01-12
LMA3X(X:10,15,20,25,30,40,50) - Laryngeal Mask Airway X: Specification (10:1.0,15:1.5,20:2.0,25:2.5,30:3.0,40:4.0,50:5.0)	Class IIa		2023-01-12
LMA4X(X:10,15,20,25,30,40,50) - Laryngeal Mask Airway X: Specification (10:1.0,15:1.5,20:2.0,25:2.5,30:3.0,40:4.0,50:5.0)	Class IIa		2023-01-12
LMAE3X(X:30,40,50) - Laryngeal Mask Airway X: Specification (30:3.0,40:4.0,50:5.0)	Class IIa		2023-01-12
LMAV4X(X:30,40,50) - Laryngeal Mask Airway X: Specification (30:3.0,40:4.0,50:5.0)	Class IIa		2023-01-12
Basic UDI-DI: 693811937356K5			
SMBX(X:000,001,002,003,004,005) - Anesthesia mask X:Specification(000:0#; 001:1#; 002:2#； 003:3#; 004:4#; 005:5#)	Class IIa R03010101		2023-02-24
SMDX(X:003,004,005） - Anesthesia mask X:Specification(003:3#; 004:4#; 005:5#)	Class IIa R03010101		2023-02-24

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Basic UDI-DI: 693811937357K7			
EM100310 - Anesthesia mask	Class IIa R03010101		2023-02-24
EM100412 - Anesthesia mask	Class IIa R03010101		2023-02-24
EM100510 - Anesthesia mask	Class IIa R03010101		2023-02-24
EM100512 - Anesthesia mask	Class IIa R03010101		2023-02-24
Basic UDI-DI: 693811937358K9			
AMEX(X: 003,004,005） - Anesthesia mask X:Specification(003:3#; 004:4#; 005:5#)	Class IIa R03010101		2023-02-24
AMHX(X:001,002,003,004,005,006） - Anesthesia mask X:Specification(001:1#; 002:2#; 003:3#; 004：4#; 005:5#; 006:6#)	Class IIa R03010101		2023-02-24
AMSX(X:000,001,002,003,004,005,006）- Anesthesia mask X:Specification(000:0#; 001:1#; 002:2#; 003:3#; 004：4#; 005:5#; 006:6#)	Class IIa R03010101		2023-02-24
IAMX(X:000,001,002,003,004,005,006）- Anesthesia mask X:Specification(000:0#; 001:1#; 002:2#; 003:3#; 004：4#; 005:5#; 006:6#)	Class IIa R03010101		2023-02-24
Basic UDI-DI: 693811937359KB			
BC3BXY(X: A, C; Y: 120, 150, 160, 180, 200) - Breathing Circuit X: Sub-type (A:Adult; C:Child)Y: Length (120:1.2m; 150:1.5m; 160:1.6m; 180:1.8m; 200:2.0m)	Class IIa R02010101		2023-02-24
BCBXY (X: A, C; Y: 120, 150, 160, 180, 200) - Breathing Circuit X: Sub-type (A:Adult; C:Child)Y: Length (120:1.2m; 150:1.5m; 160:1.6m; 180:1.8m; 200:2.0m)	Class IIa R02010101		2023-02-24
BCMXY (X: A, C; Y: 120, 150, 160, 180, 200) - Breathing Circuit X: Sub-type (A:Adult; C:Child)Y: Length (120:1.2m; 150:1.5m; 160:1.6m; 180:1.8m; 200:2.0m)	Class IIa R02010199		2023-02-24
BCW3BXY (X: A, C; Y: 120, 150, 160, 180, 200) - Breathing Circuit X: Sub-type (A:Adult; C:Child)Y: Length (120:1.2m; 150:1.5m; 160:1.6m; 180:1.8m; 200:2.0m)	Class IIa R02010102		2023-02-24

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BCWBXY (X: A, C; Y: 120, 150, 160, 180, 200) - Breathing Circuit X: Sub-type (A:Adult; C:Child)Y: Length (120:1.2m; 150:1.5m; 160:1.6m; 180:1.8m; 200:2.0m)	Class IIa R02010102		2023-02-24
BCWXY(X: A, C; Y: 120, 150, 160, 180, 200) - Breathing Circuit X: Sub-type (A:Adult; C:Child)Y: Length (120:1.2m; 150:1.5m; 160:1.6m; 180:1.8m; 200:2.0m)	Class IIa R02010102		2023-02-24
BCXY (X: A, C; Y: 120, 150, 160, 180, 200) - Breathing Circuit X: Sub-type (A:Adult; C:Child)Y: Length (120:1.2m; 150:1.5m; 160:1.6m; 180:1.8m; 200:2.0m)	Class IIa R02010101		2023-02-24
Basic UDI-DI: 693811937360JU			
BR3BXY(X: A, C; Y: 120, 150, 160, 180, 200) - Breathing Circuit X: Sub-type (A:Adult; C:Child)Y: Length (120:1.2m; 150:1.5m; 160:1.6m; 180:1.8m; 200:2.0m)	Class IIa R02010101		2023-02-24
BRBXY (X: A, C; Y: 120, 150, 160, 180, 200) - Breathing Circuit X: Sub-type (A:Adult; C:Child)Y: Length (120:1.2m; 150:1.5m; 160:1.6m; 180:1.8m; 200:2.0m)	Class IIa R02010101		2023-02-24
BRW3BXY (X: A, C; Y: 120, 150, 160, 180, 200) - Breathing Circuit X: Sub-type (A:Adult; C:Child)Y: Length (120:1.2m; 150:1.5m; 160:1.6m; 180:1.8m; 200:2.0m)	Class IIa R02010102		2023-02-24
BRWBXY (X: A, C; Y: 120, 150, 160, 180, 200) - Breathing Circuit X: Sub-type (A:Adult; C:Child)Y: Length (120:1.2m; 150:1.5m; 160:1.6m; 180:1.8m; 200:2.0m)	Class IIa R02010102		2023-02-24
BRWXY(X: A, C; Y: 120, 150, 160, 180, 200) - Breathing Circuit X: Sub-type (A:Adult; C:Child)Y: Length (120:1.2m; 150:1.5m; 160:1.6m; 180:1.8m; 200:2.0m)	Class IIa R02010102		2023-02-24
BRXY (X: A, C; Y: 120, 150, 160, 180, 200) - Breathing Circuit X: Sub-type (A:Adult; C:Child)Y: Length (120:1.2m; 150:1.5m; 160:1.6m; 180:1.8m; 200:2.0m)	Class IIa R02010101		2023-02-24
Basic UDI-DI: 693811937361JW			

[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

Certificate number: 28620139578-01
Product list issue date: 24 February 2023

Product	Classification and EMDN	Intended use[1]	Date Added
BE3BXY(X: A, C; Y: 120, 150, 160, 180, 200) - Breathing Circuit X: Sub-type (A:Adult; C:Child)Y: Length (120:1.2m; 150:1.5m; 160:1.6m; 180:1.8m; 200:2.0m)	Class IIa R02010101		2023-02-24
BEBXY (X: A, C; Y: 120, 150, 160, 180, 200) - Breathing Circuit X: Sub-type (A:Adult; C:Child)Y: Length (120:1.2m; 150:1.5m; 160:1.6m; 180:1.8m; 200:2.0m)	Class IIa R02010101		2023-02-24
BEW3BXY (X: A, C; Y: 120, 150, 160, 180, 200) - Breathing Circuit X: Sub-type (A:Adult; C:Child)Y: Length (120:1.2m; 150:1.5m; 160:1.6m; 180:1.8m; 200:2.0m)	Class IIa R02010102		2023-02-24
BEWBXY (X: A, C; Y: 120, 150, 160, 180, 200) - Breathing Circuit X: Sub-type (A:Adult; C:Child)Y: Length (120:1.2m; 150:1.5m; 160:1.6m; 180:1.8m; 200:2.0m)	Class IIa R02010102		2023-02-24
BEWXY(X: A, C; Y: 120, 150, 160, 180, 200) - Breathing Circuit X: Sub-type (A:Adult; C:Child)Y: Length (120:1.2m; 150:1.5m; 160:1.6m; 180:1.8m; 200:2.0m)	Class IIa R02010102		2023-02-24
BEXY (X: A, C; Y: 120, 150, 160, 180, 200) - Breathing Circuit X: Sub-type (A:Adult; C:Child)Y: Length (120:1.2m; 150:1.5m; 160:1.6m; 180:1.8m; 200:2.0m)	Class IIa R02010101		2023-02-24
Basic UDI-DI: 693811937362JY			
BCDY (Y: 120, 150, 160, 180, 200) - Breathing Circuit Y: Length (120:1.2m; 150:1.5m; 160:1.6m; 180:1.8m; 200:2.0m)	Class IIa R020199		2023-02-24
Basic UDI-DI: 693811937363K2			
BCMD250 - Breathing Circuit	Class IIa R020199		2023-02-24
Basic UDI-DI: 693811937364K4			
BCNWXY (X: A, C; Y: 120, 150, 160, 180, 200) - Breathing Circuit X: Sub-type (A:Adult; C:Child)Y: Length (120:1.2m; 150:1.5m; 160:1.6m; 180:1.8m; 200:2.0m)	Class IIa R020199		2023-02-24

[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

Certificate number: 28620139578-01
Product list issue date: 24 February 2023

Product	Classification and EMDN	Intended use[1]	Date Added
BCNXY (X: A, C; Y: 120, 150, 160, 180, 200) - Breathing Circuit X: Sub-type (A:Adult; C:Child)Y: Length (120:1.2m; 150:1.5m; 160:1.6m; 180:1.8m; 200:2.0m)	Class IIa R020199		2023-02-24
BRNWXY (X: A, C; Y: 120, 150, 160, 180, 200) - Breathing Circuit X: Sub-type (A:Adult; C:Child)Y: Length (120:1.2m; 150:1.5m; 160:1.6m; 180:1.8m; 200:2.0m)	Class IIa R020199		2023-02-24
BRNXY (X: A, C; Y: 120, 150, 160, 180, 200) - Breathing Circuit X: Sub-type (A:Adult; C:Child)Y: Length (120:1.2m; 150:1.5m; 160:1.6m; 180:1.8m; 200:2.0m)	Class IIa R020199		2023-02-24
Basic UDI-DI: 693811937365K6			
HMEA00 - Heat and Moisture Exchanger	Class IIa R040299		2023-02-24
HMEC00 - Heat and Moisture Exchanger	Class IIa R040299		2023-02-24
IHME00 - Heat and Moisture Exchanger	Class IIa R040299		2023-02-24
Basic UDI-DI: 693811937366K8			
HMET00 - Heat and Moisture Exchanger	Class IIa R040201		2023-02-24
Basic UDI-DI: 693811937367KA			
IMRP000 - Manual Resuscitator	Class IIa R03020201		2023-02-24
MRPA000 - Manual Resuscitator	Class IIa R03020201		2023-02-24
MRPC000 - Manual Resuscitator	Class IIa R03020201		2023-02-24
Basic UDI-DI: 693811937368KC			
IMRS000 - Manual Resuscitator	Class IIa R03020201		2023-02-24
MRSA000 - Manual Resuscitator	Class IIa R03020201		2023-02-24
MRSC000 - Manual Resuscitator	Class IIa R03020201		2023-02-24

[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

Certificate number: 28620139578-01
Product list issue date: 24 February 2023

Product	Classification and EMDN	Intended use[1]	Date Added

Brian Mather
Certification Authority, MDR
Intertek Medical Notified Body AB, Torshamnsgatan 43,
Box 1103, SE-164 22 Kista, Sweden

[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

Certificate number: 28620139578-01
Product list issue date: 24 February 2023

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 073403 0025 Rev. 03

Manufacturer:

Henan Tuoren Medical Device Co., Ltd.
Weiyuan Industrial Zone
Menggang, Changyuan County
453400 Henan
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

Endotracheal Tube, Tracheotomy Tube, Endobronchial Tube, Infusion Pump, I.V. Cannula, Reinforced Endotracheal Tube, Laryngeal Mask Airway, Foley Catheter Kit, Suction Catheter, Breathing Circuit, Oxygen Mask, Anesthesia Mask, Guedel Airway, Endotracheal Intubation Kit, Nasal Oxygen Tube, Heat and Moisture Exchanger, Suction Handle, Manual Resuscitator, LOR Indicator Syringe, Disposable Pressure Transducer.

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: BJ1973704

Valid from: 2019-11-21
Valid until: 2024-05-26

Date, 2019-11-21

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 073403 0025 Rev. 03

Facility(ies):

Henan Tuoren Medical Device Co., Ltd.
Weiyuan Industrial Zone, Menggang, Changyuan County, 453400
Henan, PEOPLE'S REPUBLIC OF CHINA

Henan Tuoren Medical Device Co., Ltd.
Middle of Weft 7 Road, Nanpu District, 453400 Changyuan
County, Henan, PEOPLE'S REPUBLIC OF CHINA

Henan Tuoren Medical Device Co., Ltd.
Mancun Industrial Zone, Changyuan County, 453400 Henan,
PEOPLE'S REPUBLIC OF CHINA

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

CE SERTIFIKATAS

Pilna kokybės užtikrinimo sistema
Medicinos prietaisų direktyva 93/42/EEC (MDD), II priedas, išskyrus (4)
(Įrenginiai klasėje IIa, IIb arba III)
Nr. G1 073403 0025 Rev. 03

Gamintojas: Henan Tuoren Medical Devices Co., Ltd.
Weiyuan industrnė zona
Menggang, Changyuan County
453400 Henan,
Kinijos Liaudies Respublika

Produkto kategorijos: Endotrachėjniai vamzdeliai, Tracheostominiai vamzdeliai, Endobronchiniai vamzdeliai, Infuzinės pompos, I.V. Kaniulės, Sustiprinti endrotrechėjiniai vamzdeliai, Gerklų kaukė kvėpavimo takams, Foley kateterių rinkiniai, Atsiurbimo kateteriai, Kvėpavimo kontūras, Deguonies kaukė, Anestezinė kaukė, Guedel Airway, Endotrachėjinis intubacinis rinkinys, Nosies deguonies vamzdelis, Šilumos ir drėgmės keitiklis, Atsiurbimo rankenėlė, Rankinis gaivinimo aparatas, LOR indikatoriaus švirkštas, Vienkartinis slėgio keitiklis.

Pranešimo numeris: BJ1973704

Galioja nuo: 2019-11-21
Galioja iki: 2024-05-26

Data, 2019-11-21

Parašas//
Christoph Dicks
Sertifikavimo / Notifikuotosios įstaigos vadovas

CE SERTIFIKATAS

Pilna kokybės užtikrinimo sistema
Medicinos prietaisų direktyva 93/42/EEC (MDD), II priedas, išskyrus (4)
(Įrenginiai klasėje IIa, IIb arba III)
Nr. G1 073403 0025 Rev. 03

Paslaugos: Henan Tuoren Medical Devices Co., Ltd.

Weiyuan Industinė zona, Menggang, Changyuan County, 453400

Henan, Kinijos Liaudies Respublika

Henan Tuoren Medical Devices Co., Ltd.

Middle of Weft 7 Road, Nanou District, 453400 Changyuan

County, Henan, Kinijos Liaudies Respublika

Henan Tuoren Medical Devices Co., Ltd.

Mancun Industrinė Zona, Changyuan County, 453400, Henan,

Kinijos Liaudies Respublika

Mirandola, 24 May 2024

Subject: **CE extension according to Regulation 2023/607**

We hereby declare that the medical devices manufactured by **HMC Premedical SpA** comply with Directive 93/42/EEC and subsequent updates.

The CE certificates n° 1668/MDD and 1669/MDD relating to these medical devices, issued by the Notified Body n° 0051 – IMQ SpA with expiration 18/04/2024, cannot be updated.

For such medical devices, provided that the following conditions are met:

(a) the devices continue to comply with Directive 93/42/EEC;
(b) there are no significant changes in the design and intended purpose;
(c) the devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health;
(d) no later than 26 May 2024, the manufacturer has put in place a quality management system in accordance with Article 10(9) of Regulation 2017/745 (MDR);
(e) no later than 26 May 2024, the manufacturer or authorized representative has lodged a formal application with a Notified Body in accordance with the Regulation, for conformity assessment in respect of a device and, no later than 26 September 2024, the Notified Body and the manufacturer have signed a written agreement in accordance as indicated in the regulation.

Regulation 2023/607 has extended the validity of CE certificates until 31 December 2028, with the consequent possibility of placing the relevant medical devices on the market until that date.

HMC Premedical SpA confirms that all the above conditions are satisfied and that the necessary activities have been completed and confirmed by the Notified Body n° 0051 – IMQ SpA to which the MDR certification application has been submitted and with which the written agreement is in force.

By 26 September 2024, the Notified Body will prepare the “confirmation letter” which will provide additional confirmation of what is already legally valid as a result of Regulation 2023/607.

HMC Premedical SpA

CERTIFICATO CE

Certificato n. 1668/MDD

Dichiarazione di approvazione del sistema qualità

(Sistema completo di garanzia qualità)

Visto l'esito delle verifiche condotte in conformità all'Allegato II, con l'esclusione del punto 4, della direttiva 93/42/CEE e s.m.i., si dichiara che la ditta:

HMC PREMEDICAL SPA

41037 MIRANDOLA (MO) - VIA BOSCO 1/3 (ITA) - Italy

mantiene nello stabilimento di:

41037 MIRANDOLA (MO) - VIA BOSCO 1/3 (ITA) - Italy

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

un sistema qualità che assicura la conformità dei seguenti prodotti:

Kit procedurali

Linee per dialisi e accessori

Sistemi per nutrizione enterale e parenterale e accessori

Circuiti per foto immuno terapia

Dispositivi per trasfusione e accessori

Dispositivi per infusione e accessori – set per infusione farmaci antiblastici

Sistemi di drenaggio toracico e post operatorio

Sistemi di lavaggio

Sonde nasogastriche

Surfactant Kit

Sonde e cannule rettali

Set di produzione, dispensazione, infusione ed accessori

Sistemi di aspirazione non attivi

serie e modelli indicati in Allegato

ai requisiti essenziali della direttiva suddetta ad essi applicabili (in tutte le fasi dalla progettazione al controllo finale) ed è sottoposta alla sorveglianza prevista dal punto 5 dell'Allegato II. Per i dispositivi in classe III questo certificato è valido solamente con il relativo certificato di esame CE della progettazione di Allegato II.4.

Emesso il:	2014-04-22
Data aggiornamento:	2021-05-07
Sostituisce:	2021-03-19
Data scadenza:	2024-04-18

IMQ

CERTIFICATO CE

Certificato n. 1668/MDD

Dichiarazione di approvazione del sistema qualità

(Sistema completo di garanzia qualità)

Riferimento pratiche IMQ:

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.

Questa Dichiarazione di approvazione è rilasciata dall'IMQ S.p.A. quale organismo notificato per la direttiva 93/42/CEE e s.m.i. Il numero identificativo dell'IMQ S.p.A. quale organismo notificato è: 0051.

Emesso il:	2014-04-22
Data aggiornamento:	2021-05-07
Sostituisce:	2021-03-19
Data scadenza:	2024-04-18

IMQ

CERTIFICATO CE

Certificato n. 1668/MDD

Allegato

Kit procedurali

Linee per dialisi e accessori

Sistemi per nutrizione enterale e parenterale e accessori

Circuiti per foto immuno terapia

Dispositivi per trasfusione e accessori

Dispositivi per infusione e accessori – set per infusione farmaci antiblastici

Sistemi di drenaggio toracico e post operatorio

Sistemi di lavaggio

Sonde nasogastriche

Surfactant Kit

Sonde e cannule rettali

Set di produzione, dispensazione, infusione ed accessori

Sistemi di aspirazione non attivi

Modd. come da documento "Allegato al Certificato CE n. 1668/MDD - Elenco dei Dispositivi" rev. 0 del 2021/03/19; tale allegato costituisce parte integrante e sostanziale del presente certificato.

Emesso il:	2014-04-22
Data aggiornamento:	2021-05-07
Sostituisce:	2021-03-19
Data scadenza:	2024-04-18

IMQ

EC CERTIFICATE

Certificate No 1668/MDD

Full Quality Assurance System Approval Certificate

On the basis of our examination carried out according to Annex II, excluding section 4, of the Directive 93/42/EEC and its revised version, we hereby certify that:

HMC PREMEDICAL SPA

41037 MIRANDOLA (MO) - VIA BOSCO 1/3 (ITA) - Italy

manages in the factory of:

41037 MIRANDOLA (MO) - VIA BOSCO 1/3 (ITA) - Italy

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

a quality assurance system ensuring the conformity of the following products:

Custom procedure Trays

Lines for dialysis and accessories

Enteral and parenteral nutrition systems and accessories

Photo immuno therapy kit

Transfusion sets and accessories

Infusion sets and accessories – infusion sets for antiblastic drugs

Thoracic drainage and post operative systems

Washing systems

Nasogastric tubes

Surfactant Kit

Rectal tubes and straws

Set for production, dispensation, infusion and accessories

Not active suction systems

series and type refs in the Annex

with the relevant essential requirements of the aforementioned directive (from design to final inspection and testing) and it is subject to surveillance as specified in section 5 of Annex II. For class III devices, this certificate is valid only with the relevant EC Design-Examination Certificate of Annex II.4.

Date:	2014-04-22
Updated:	2021-05-07
Substitution Date:	2021-03-19
Expiry Date:	2024-04-18

IMQ

DocuSign

EC CERTIFICATE

Certificate No 1668/MDD

Full Quality Assurance System Approval Certificate

Reference to IMQ files Nos:

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.

This Approval Certificate is issued by IMQ S.p.A. as Notified Body for the Directive 93/42/EEC and its revised version. Notified Body notified to European Commission under number: 0051.

Date:	2014-04-22
Updated:	2021-05-07
Substitution Date:	2021-03-19
Expiry Date:	2024-04-18

IMQ

EC CERTIFICATE

Certificate No 1668/MDD

Annex

Custom procedure Trays

Lines for dialysis and accessories

Enteral and parenteral nutrition systems and accessories

Photo immuno therapy kit

Transfusion sets and accessories

Infusion sets and accessories – infusion sets for antiblastic drugs

Thoracic drainage and post operative systems

Washing systems

Nasogastric tubes

Surfactant Kit

Rectal tubes and straws

Set for production, dispensation, infusion and accessories

Not active suction systems

Type ref. as to document "Annex of EC Certificate no. 1668/MDD - Device List" rev. 0 dated 2021/03/19; this annex is integral and substantial part of this certificate.

Date:	2014-04-22
Updated:	2021-05-07
Substitution Date:	2021-03-19
Expiry Date:	2024-04-18

IMQ

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:	**Kit procedurali** Custom procedure Trays
Modello/i: Model(s):	**Kit per cardiologia e cardiochirurgia, ortopedia, radiologia, dermatologia, ostetricia e ginecologia, neurochirurgia, otorinolaringoiatria, medicazione, urologia, oftalmologia, anestesia, elettrofisiologia, chirurgia generale:** Kit for cardiology and cardiac surgery, orthopedics, radiology, dermatology, obstetrics and gynecology, neurosurgery, otolaryngology, medication, urology, ophthalmology, anesthesiology, electrophysiology, general surgery: **Codice** / Code: • **KIT/xx(y)(y)(y)(y)(y)(y)(y)(y)(y)(y)** **dove** / where: **xx = Carattere numerico** / Numeric character **y = Carattere alfanumerico (massimo 10 caratteri)** / Alphanumeric character (max. 10 characters) **Possibile inserimento di simboli (barra, punto, asterisco, etc) all'interno dei codici** Possible insertion of symbols (slash, dot, asterisk, etc.) inside the code
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:	**Linee per dialisi e accessori** Lines for dialysis and accessories
Modello/i: Model(s):	**Codici** / Codes: • **DLS/xxxy** • **HPF 6414** • **P5L** • **P5L-3V** • **10xx** • **10xx-y** • **BHxxx** • **PT/9xx-NL** **dove** / where: **xx(x) = Carattere numerico e può assumere i seguenti valori: da (0)01 a (9)99 /** Numeric character and can assume the following values: from (0)01 to (9)99 **y = Varie tipologie di componentistica /** Different combinations of components **DLS = Dispositivo linee sangue /** Device blood-line
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 per nutrizione enterale e parenterale e accessori** Enteral and parenteral nutrition systems and accessories
Modello/i: Model(s):	**Sacche per nutrizione enterale e parenterale /** Enteral and parenteral nutrition bags **Codice** / Code: • **BAG/yxxxx** **dove /** where: **BAG = Sacche per nutrizione enterale e parenterale /** Enteral and parenteral nutrition bags **y = identifica il tipo di sacca e può assumere i seguenti valori /** identifies the bag type and can assume the following values: • **P = Parenterale /** Parenteral • **E = Enterale /** Enteral **xxxx = Varie tipologie di componentistica /** Different combinations of components
Modello/i: Model(s):	**Set per nutrizione enterale /** Enteral feeding set **Codici /** Codes: • **Cxxx(M)** • **CxxxL** • **OCxxx(M)** • **OHCxxx** • **EPxxx(y)(y)** • **EPxxxL** • **EPxxxLY** • **EPxxxLW** • **EPxxxLYW** • **EVnn(L)** • **OEPxxx(y)(y)** • **MBSnn(L)** • **MGSnn(L)** • **MFxxx(y)(y)(y)** • **RSnn** • **LSnn** • **BASnnL** • **DPbb/aa** **dove /** where: **xxx = variante numerica lunghezza dei tubi in cm /** numeric variable for tube's length in centimeters **a/aa = variante numerica (1 o 2 cifre) della quantità di prodotti /** variable (1 or 2 numbers) for products quantity **bb = variante numerica della capacità del prodotto /** variable for product capacity **nn = numero progressivo che indica versioni differenti /** progressive number which indicates different versions **y = indica una versione differente /** indicates a different version **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

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 per nutrizione enterale e parenterale e accessori** Enteral and parenteral nutrition systems and accessories
Modello/i: Model(s):	**Accessori di Set per nutrizione enterale: /** Accessories of Enteral feeding set: **Codici /** Codes: • **20-110-aa/D** • **M158/a(L)** • **M158/aLD** • **OM158/aa** • **M19400/D** • **LK01** • **OM19400** • **OM19400/V** • **(O)MLnn** • **MLnn(L)** • **(O)MFnn(M)** • **MFnn(L)** • **MD/PE** • **PE/MD** • **BAnn(L)** • **BAnnB(L)** • **OTBAnn** • **OTCaa** • **(O)MNnn(M)** • **MNnn(L)** • **TAnn** • **SAnn(L)** **dove /** where: **D = variabile che indica il colore del prodotto /** variable which indicates the colour of the product **xxx = variante numerica lunghezza dei tubi in cm /** numeric variable for tube's length in centimeters **a/aa = variante numerica (1 o 2 cifre) della quantità di prodotti /** variable (1 or 2 numbers) for products quantity **nn = numero progressivo che indica versioni differenti /** progressive number which indicates different 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**