

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that: Henan Tuoren Best Medical Device Co., Ltd.
Middle of Weft 7 Road
Nanpu District
Changyuan
Henan
453400
China

河南驼人贝斯特医疗器械有限公司
中国
河南省
长垣市
南蒲街道办事处
纬七路中段路南
邮编: 453400

Holds Certificate No: **MD 735978**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design & Development, Manufacture and Distribution of Sterile and Non-Sterile Disposable Medical Isolation Gowns, Disposable Medical Protective Coveralls, Medical Silicone Masks, Medical Protective Hoods, Surgical Face Masks and Sterile Central Venous Catheter (CVC) Kits.
无菌和非无菌的一次性使用隔离衣、医用一次性防护服、医用硅胶外科口罩、医用防护头罩、医用外科口罩以及无菌中心静脉导管包的设计开发、生产和销售。



For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2021-05-09

Latest Revision Date: 2021-05-09

Effective Date: 2021-05-09

Expiry Date: 2024-05-08

Page: 1 of 1



...making excellence a habit.™

Henan Tuoren Best Medical Device Co., Ltd.

Document Title: EU Declaration of Conformity of 2017/745 (MDR)

Document Number: BST-CE-06-02

Revision: A0

Author: Shi Wenping

Date: 2021-05-15

REVISION STATUS:

Version	Brief Description of Revision	Author	Date
A0	New Procedure	Shi Wenping	2021-05-15

Prepared by/Date: Shi Wenping 2021-05-15

Reviewed by/Date: Luo Haikun 2021-05-15

Approved by/Date: Miao Jingmei 2021-05-15

EU Declaration of Conformity

Manufacturer: Henan Tuoren Best Medical Device Co., Ltd.

Address: Middle of Weft 7 Road, Nanpu District, 453400 Changyuan, Henan, P.R.China

Tel.: +86 0373-8814000 **Fax:**+86 0373-8816222

SRN: CN-MF-000007452

European representative: Lotus NL B.V.

Address: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

Tel: +31644168999 **Fax:**008621-58857798

SRN: NL-AR-000000121

Product: Central Venous Catheter (CVC) Kit

Brand name: /

Device Nomenclature Code: C010202

Basic UDI-DI:694242711359FE

Model List: See Annex 1

Applied Standards List: See Annex 2

Classification: According to Classification Rule 7, Annex VIII of (EU) 2017/745 (MDR), the Central Venous Catheter (CVC) Kit is in Class III.

Conformity Assessment Route: Chapters I and III of Annex IX, and including an assessment of the technical documentation as specified in Section 4 of that Annex, Regulation (EU) 2017/745 (MDR)

We hereby declare that the above mentioned product meet the provisions of the Regulation (EU) 2017/745 (MDR) for medical devices. No medicinal product, including a medicinal product derived from human blood or human plasma, no tissues or cells of human origin or their derivatives, no CMR or endocrine-disrupting substances are incorporated into the device. All supporting documentation is retained under the premises of the manufacturer and Notified Body.

CE XXXX

Certificate	Initially issued	Last renewal	Valid until
Full Quality Assurance System Certificate No.: MDR734120	\	\	\

The EU Declaration of Conformity is issued under the sole responsibility of the manufacturer:

Henan Tuoren Best Medical Device Co., Ltd.

Signed for and on behalf of :

Name :

Function (Company) :

Management Representative

Date :

Location :

Henan



Annex 1 Catalogue Number List
Table 1 Specifications of Central Venous Catheter (CVC) Kit

REF	Type specifications	Specification											
		Central Venous Catheter	Guide wire	Dilator	Introducer Needle		Fastener	Hypodermic Syringe		Blue introducer syringe	Hypodermic Needle	Scalpel	Injection site cap
					Y Model	I Model		I Model	II Model				
CVMY12208	1-22Ga-8cm-Y	1-22Ga-8cm	0.018"*60cm	4Fr*5cm	20Ga	-	22Ga	5mL	5mL	-	0.7mm	11#	Regular
ICVM12208	1-22Ga-8cm-I	1-22Ga-8cm	0.018"*60cm	4Fr*5cm	-	20Ga	22Ga	5mL	-	5mL	0.7mm	11#	Regular
CVMY12213	1-22Ga-13cm-Y	1-22Ga-13cm	0.018"*60cm	4Fr*5cm	20Ga	-	22Ga	5mL	5mL	-	0.7mm	11#	Regular
ICVM12213	1-22Ga-13cm-I	1-22Ga-13cm	0.018"*60cm	4Fr*5cm	-	20Ga	22Ga	5mL	-	5mL	0.7mm	11#	Regular
CVMY12216	1-22Ga-16cm-Y	1-22Ga-16cm	0.018"*60cm	4Fr*5cm	20Ga	-	22Ga	5mL	5mL	-	0.7mm	11#	Regular
ICVM12216	1-22Ga-16cm-I	1-22Ga-16cm	0.018"*60cm	4Fr*5cm	-	20Ga	22Ga	5mL	-	5mL	0.7mm	11#	Regular
CVMY12220	1-22Ga-20cm-Y	1-22Ga-20cm	0.018"*60cm	4Fr*5cm	20Ga	-	22Ga	5mL	5mL	-	0.7mm	11#	Regular
ICVM12220	1-22Ga-20cm-I	1-22Ga-20cm	0.018"*60cm	4Fr*5cm	-	20Ga	22Ga	5mL	-	5mL	0.7mm	11#	Regular
CVMY12230	1-22Ga-30cm-Y	1-22Ga-30cm	0.018"*60cm	4Fr*5cm	20Ga	-	22Ga	5mL	5mL	-	0.7mm	11#	Regular
ICVM12230	1-22Ga-30cm-I	1-22Ga-30cm	0.018"*60cm	4Fr*5cm	-	20Ga	22Ga	5mL	-	5mL	0.7mm	11#	Regular
CVMY12013	1-20Ga-13cm-Y	1-20Ga-13cm	0.021"*60cm	4Fr*5cm	20Ga	-	20Ga	5mL	5mL	-	0.7mm	11#	Regular
ICVM12013	1-20Ga-13cm-I	1-20Ga-13cm	0.021"*60cm	4Fr*5cm	-	20Ga	20Ga	5mL	-	5mL	0.7mm	11#	Regular
CVMY12016	1-20Ga-16cm-Y	1-20Ga-16cm	0.021"*60cm	4Fr*5cm	20Ga	-	20Ga	5mL	5mL	-	0.7mm	11#	Regular
ICVM12016	1-20Ga-16cm-I	1-20Ga-16cm	0.021"*60cm	4Fr*5cm	-	20Ga	20Ga	5mL	-	5mL	0.7mm	11#	Regular
CVMY12020	1-20Ga-20cm-Y	1-20Ga-20cm	0.021"*60cm	4Fr*5cm	20Ga	-	20Ga	5mL	5mL	-	0.7mm	11#	Regular
ICVM12020	1-20Ga-20cm-I	1-20Ga-20cm	0.021"*60cm	4Fr*5cm	-	20Ga	20Ga	5mL	-	5mL	0.7mm	11#	Regular
CVMY11813	1-18Ga-13cm-Y	1-18Ga-13cm	0.021"*60cm	5.5Fr*6cm	20Ga	-	18Ga	5mL	5mL	-	0.7mm	11#	Regular

REF	Type specifications	Specification											
		Central Venous Catheter	Guide wire	Dilator	Introducer Needle		Fastener	Hypodermic Syringe		Blue introducer syringe	Hypodermic Needle	Scalpel	Injection site cap
					Y Model	I Model		I Model	II Model				
ICVM11813	1-18Ga-13cm-I	1-18Ga-13cm	0.021"*60cm	5.5Fr*6cm	-	20Ga	18Ga	5mL	-	5mL	0.7mm	11#	Regular
CVMY11816	1-18Ga-16cm-Y	1-18Ga-16cm	0.021"*60cm	5.5Fr*6cm	20Ga	-	18Ga	5mL	5mL	-	0.7mm	11#	Regular
ICVM11816	1-18Ga-16cm-I	1-18Ga-16cm	0.021"*60cm	5.5Fr*6cm	-	20Ga	18Ga	5mL	-	5mL	0.7mm	11#	Regular
CVMY11820	1-18Ga-20cm-Y	1-18Ga-20cm	0.021"*60cm	5.5Fr*6cm	20Ga	-	18Ga	5mL	5mL	-	0.7mm	11#	Regular
ICVM11820	1-18Ga-20cm-I	1-18Ga-20cm	0.021"*60cm	5.5Fr*6cm	-	20Ga	18Ga	5mL	-	5mL	0.7mm	11#	Regular
CVMY11616	1-16Ga-16cm-Y	1-16Ga-16cm	0.035"*60cm	6.5Fr*10cm	18Ga	-	16Ga	5mL	5mL	-	0.7mm	11#	Regular
ICVM11616	1-16Ga-16cm-I	1-16Ga-16cm	0.035"*60cm	6.5Fr*10cm	-	18Ga	16Ga	5mL	-	5mL	0.7mm	11#	Regular
CVMY11620	1-16Ga-20cm-Y	1-16Ga-20cm	0.035"*60cm	6.5Fr*10cm	18Ga	-	16Ga	5mL	5mL	-	0.7mm	11#	Regular
ICVM11620	1-16Ga-20cm-I	1-16Ga-20cm	0.035"*60cm	6.5Fr*10cm	-	18Ga	16Ga	5mL	-	5mL	0.7mm	11#	Regular
CVMY11630	1-16Ga-30cm-Y	1-16Ga-30cm	0.035"*60cm	6.5Fr*10cm	18Ga	-	16Ga	5mL	5mL	-	0.7mm	11#	Regular
ICVM11630	1-16Ga-30cm-I	1-16Ga-30cm	0.035"*60cm	6.5Fr*10cm	-	18Ga	16Ga	5mL	-	5mL	0.7mm	11#	Regular
CVMY11416	1-14Ga-16cm-Y	1-14Ga-16cm	0.035"*60cm	8Fr*10cm	18Ga	-	14Ga	5mL	5mL	-	0.7mm	11#	Regular
ICVM11416	1-14Ga-16cm-I	1-14Ga-16cm	0.035"*60cm	8Fr*10cm	-	18Ga	14Ga	5mL	-	5mL	0.7mm	11#	Regular
CVMY11420	1-14Ga-20cm-Y	1-14Ga-20cm	0.035"*60cm	8Fr*10cm	18Ga	-	14Ga	5mL	5mL	-	0.7mm	11#	Regular
ICVM11420	1-14Ga-20cm-I	1-14Ga-20cm	0.035"*60cm	8Fr*10cm	-	18Ga	14Ga	5mL	-	5mL	0.7mm	11#	Regular
CVMY11430	1-14Ga-30cm-Y	1-14Ga-30cm	0.035"*60cm	8Fr*10cm	18Ga	-	14Ga	5mL	5mL	-	0.7mm	11#	Regular
ICVM11430	1-14Ga-30cm-I	1-14Ga-30cm	0.035"*60cm	8Fr*10cm	-	18Ga	14Ga	5mL	-	5mL	0.7mm	11#	Regular
CVMY11216	1-12Ga-16cm-Y	1-12Ga-16cm	0.035"*60cm	8.5Fr*10cm	18Ga	-	8Fr	5mL	5mL	-	0.7mm	11#	Regular

REF	Type specifications	Specification											
		Central Venous Catheter	Guide wire	Dilator	Introducer Needle		Fastener	Hypodermic Syringe		Blue introducer syringe	Hypodermic Needle	Scalpel	Injection site cap
					Y Model	I Model		I Model	II Model				
ICVM11216	1-12Ga-16cm-I	1-12Ga-16cm	0.035"*60cm	8.5Fr*10cm	-	18Ga	8Fr	5mL	-	5mL	0.7mm	11#	Regular
CVMY11220	1-12Ga-20cm-Y	1-12Ga-20cm	0.035"*60cm	8.5Fr*10cm	18Ga	-	8Fr	5mL	5mL	-	0.7mm	11#	Regular
ICVM11220	1-12Ga-20cm-I	1-12Ga-20cm	0.035"*60cm	8.5Fr*10cm	-	18Ga	8Fr	5mL	-	5mL	0.7mm	11#	Regular
CVMY11230	1-12Ga-30cm-Y	1-12Ga-30cm	0.035"*60cm	8.5Fr*10cm	18Ga	-	8Fr	5mL	5mL	-	0.7mm	11#	Regular
ICVM11230	1-12Ga-30cm-I	1-12Ga-30cm	0.035"*60cm	8.5Fr*10cm	-	18Ga	8Fr	5mL	-	5mL	0.7mm	11#	Regular
CVMY24005	2-4Fr-05cm-Y	2-4Fr-05cm	0.018"*60cm	5.5Fr*6cm	20Ga	-	18Ga	5mL	5mL	-	0.7mm	11#	Regular
ICVM24005	2-4Fr-05cm-I	2-4Fr-05cm	0.018"*60cm	5.5Fr*6cm	-	20Ga	18Ga	5mL	-	5mL	0.7mm	11#	Regular
CVMY24008	2-4Fr-08cm-Y	2-4Fr-08cm	0.018"*60cm	5.5Fr*6cm	20Ga	-	18Ga	5mL	5mL	-	0.7mm	11#	Regular
ICVM24008	2-4Fr-08cm-I	2-4Fr-08cm	0.018"*60cm	5.5Fr*6cm	-	20Ga	18Ga	5mL	-	5mL	0.7mm	11#	Regular
CVMY24013	2-4Fr-13cm-Y	2-4Fr-13cm	0.018"*60cm	5.5Fr*6cm	20Ga	-	18Ga	5mL	5mL	-	0.7mm	11#	Regular
ICVM24013	2-4Fr-13cm-I	2-4Fr-13cm	0.018"*60cm	5.5Fr*6cm	-	20Ga	18Ga	5mL	-	5mL	0.7mm	11#	Regular
CVMY24016	2-4Fr-16cm-Y	2-4Fr-16cm	0.018"*60cm	5.5Fr*6cm	20Ga	-	18Ga	5mL	5mL	-	0.7mm	11#	Regular
ICVM24016	2-4Fr-16cm-I	2-4Fr-16cm	0.018"*60cm	5.5Fr*6cm	-	20Ga	18Ga	5mL	-	5mL	0.7mm	11#	Regular
CVMY24020	2-4Fr-20cm-Y	2-4Fr-20cm	0.018"*60cm	5.5Fr*6cm	20Ga	-	18Ga	5mL	5mL	-	0.7mm	11#	Regular
ICVM20420	2-4Fr-20cm-I	2-4Fr-20cm	0.018"*60cm	5.5Fr*6cm	-	20Ga	18Ga	5mL	-	5mL	0.7mm	11#	Regular
CVMY25013	2-5Fr-13cm-Y	2-5Fr-13cm	0.021"*60cm	5.5Fr*6cm	20Ga	-	16Ga	5mL	5mL	-	0.7mm	11#	Regular
ICVM25013	2-5Fr-13cm-I	2-5Fr-13cm	0.021"*60cm	5.5Fr*6cm	-	20Ga	16Ga	5mL	-	5mL	0.7mm	11#	Regular
CVMY25016	2-5Fr-16cm-Y	2-5Fr-16cm	0.021"*60cm	5.5Fr*6cm	20Ga	-	16Ga	5mL	5mL	-	0.7mm	11#	Regular

REF	Type specifications	Specification											
		Central Venous Catheter	Guide wire	Dilator	Introducer Needle		Fastener	Hypodermic Syringe		Blue introducer syringe	Hypodermic Needle	Scalpel	Injection site cap
					Y Model	I Model		I Model	II Model				
ICVM25016	2-5Fr-16cm-I	2-5Fr-16cm	0.021"*60cm	5.5Fr*6cm	-	20Ga	16Ga	5mL	-	5mL	0.7mm	11#	Regular
CVMY25020	2-5Fr-20cm-Y	2-5Fr-20cm	0.021"*60cm	5.5Fr*6cm	20Ga	-	16Ga	5mL	5mL	-	0.7mm	11#	Regular
ICVM25020	2-5Fr-20cm-I	2-5Fr-20cm	0.021"*60cm	5.5Fr*6cm	-	20Ga	16Ga	5mL	-	5mL	0.7mm	11#	Regular
CVMY26013	2-6Fr-13cm-Y	2-6Fr-13cm	0.021"*60cm	6.5Fr*8cm	20Ga	-	5.5Fr	5mL	5mL	-	0.7mm	11#	Regular
ICVM26013	2-6Fr-13cm-I	2-6Fr-13cm	0.021"*60cm	6.5Fr*8cm	-	20Ga	5.5Fr	5mL	-	5mL	0.7mm	11#	Regular
CVMY26016	2-6Fr-16cm-Y	2-6Fr-16cm	0.021"*60cm	6.5Fr*8cm	20Ga	-	5.5Fr	5mL	5mL	-	0.7mm	11#	Regular
ICVM26016	2-6Fr-16cm-I	2-6Fr-16cm	0.021"*60cm	6.5Fr*8cm	-	20Ga	5.5Fr	5mL	-	5mL	0.7mm	11#	Regular
CVMY26020	2-6Fr-20cm-Y	2-6Fr-20cm	0.021"*60cm	6.5Fr*8cm	20Ga	-	5.5Fr	5mL	5mL	-	0.7mm	11#	Regular
ICVM26020	2-6Fr-20cm-I	2-6Fr-20cm	0.021"*60cm	6.5Fr*8cm	-	20Ga	5.5Fr	5mL	-	5mL	0.7mm	11#	Regular
CVMY27016	2-7Fr-16cm-Y	2-7Fr-16cm	0.035"*60cm	8.5Fr*10cm	18Ga	-	7Fr	5mL	5mL	-	0.7mm	11#	Regular
ICVM27016	2-7Fr-16cm-I	2-7Fr-16cm	0.035"*60cm	8.5Fr*10cm	-	18Ga	7Fr	5mL	-	5mL	0.7mm	11#	Regular
CVMY27020	2-7Fr-20cm-Y	2-7Fr-20cm	0.035"*60cm	8.5Fr*10cm	18Ga	-	7Fr	5mL	5mL	-	0.7mm	11#	Regular
ICVM27020	2-7Fr-20cm-I	2-7Fr-20cm	0.035"*60cm	8.5Fr*10cm	-	18Ga	7Fr	5mL	-	5mL	0.7mm	11#	Regular
CVMY27030	2-7Fr-30cm-Y	2-7Fr-30cm	0.035"*60cm	8.5Fr*10cm	18Ga	-	7Fr	5mL	5mL	-	0.7mm	11#	Regular
ICVM27030	2-7Fr-30cm-I	2-7Fr-30cm	0.035"*60cm	8.5Fr*10cm	-	18Ga	7Fr	5mL	-	5mL	0.7mm	11#	Regular
CVMY28016	2-8Fr-16cm-Y	2-8Fr-16cm	0.035"*60cm	8.5Fr*10cm	18Ga	-	8Fr	5mL	5mL	-	0.7mm	11#	Regular
ICVM28016	2-8Fr-16cm-I	2-8Fr-16cm	0.035"*60cm	8.5Fr*10cm	-	18Ga	8Fr	5mL	-	5mL	0.7mm	11#	Regular
CVMY28020	2-8Fr-20cm-Y	2-8Fr-20cm	0.035"*60cm	8.5Fr*10cm	18Ga	-	8Fr	5mL	5mL	-	0.7mm	11#	Regular

REF	Type specifications	Specification											
		Central Venous Catheter	Guide wire	Dilator	Introducer Needle		Fastener	Hypodermic Syringe		Blue introducer syringe	Hypodermic Needle	Scalpel	Injection site cap
					Y Model	I Model		I Model	II Model				
ICVM28020	2-8Fr-20cm-I	2-8Fr-20cm	0.035"*60cm	8.5Fr*10cm	-	18Ga	8Fr	5mL	-	5mL	0.7mm	11#	Regular
CVMY28030	2-8Fr-30cm-Y	2-8Fr-30cm	0.035"*60cm	8.5Fr*10cm	18Ga	-	8Fr	5mL	5mL	-	0.7mm	11#	Regular
ICVM28030	2-8Fr-30cm-I	2-8Fr-30cm	0.035"*60cm	8.5Fr*10cm	-	18Ga	8Fr	5mL	-	5mL	0.7mm	11#	Regular
CVMY34008	3-4Fr-08cm-Y	3-4Fr-08cm	0.018"*60cm	5.5Fr*6cm	20Ga	-	18Ga	5mL	5mL	-	0.7mm	11#	Regular
ICVM34008	3-4Fr-08cm-I	3-4Fr-08cm	0.018"*60cm	5.5Fr*6cm	-	20Ga	18Ga	5mL	-	5mL	0.7mm	11#	Regular
CVMY34013	3-4Fr-13cm-Y	3-4Fr-13cm	0.018"*60cm	5.5Fr*6cm	20Ga	-	18Ga	5mL	5mL	-	0.7mm	11#	Regular
ICVM34013	3-4Fr-13cm-I	3-4Fr-13cm	0.018"*60cm	5.5Fr*6cm	-	20Ga	18Ga	5mL	-	5mL	0.7mm	11#	Regular
CVMY34016	3-4Fr-16cm-Y	3-4Fr-16cm	0.018"*60cm	5.5Fr*6cm	20Ga	-	18Ga	5mL	5mL	-	0.7mm	11#	Regular
ICVM34016	3-4Fr-16cm-I	3-4Fr-16cm	0.018"*60cm	5.5Fr*6cm	-	20Ga	18Ga	5mL	-	5mL	0.7mm	11#	Regular
CVMY34020	3-4Fr-20cm-Y	3-4Fr-20cm	0.018"*60cm	5.5Fr*6cm	20Ga	-	18Ga	5mL	5mL	-	0.7mm	11#	Regular
ICVM34020	3-4Fr-20cm-I	3-4Fr-20cm	0.018"*60cm	5.5Fr*6cm	-	20Ga	18Ga	5mL	-	5mL	0.7mm	11#	Regular
CVMY35508	3-5.5Fr-08cm-Y	3-5.5Fr-08cm	0.021"*60cm	6.5Fr*8cm	20Ga	-	16Ga	5mL	5mL	-	0.7mm	11#	Regular
ICVM35508	3-5.5Fr-08cm--I	3-5.5Fr-08cm	0.021"*60cm	6.5Fr*8cm	-	20Ga	16Ga	5mL	-	5mL	0.7mm	11#	Regular
CVMY35513	3-5.5Fr-13cm-Y	3-5.5Fr-13cm	0.021"*60cm	6.5Fr*8cm	20Ga	-	5.5Fr	5mL	5mL	-	0.7mm	11#	Regular
ICVM35513	3-5.5Fr-13cm-I	3-5.5Fr-13cm	0.021"*60cm	6.5Fr*8cm	-	20Ga	5.5Fr	5mL	-	5mL	0.7mm	11#	Regular
CVMY35516	3-5.5Fr-16cm-Y	3-5.5Fr-16cm	0.021"*60cm	6.5Fr*8cm	20Ga	-	5.5Fr	5mL	5mL	-	0.7mm	11#	Regular
ICVM35516	3-5.5Fr-16cm-I	3-5.5Fr-16cm	0.021"*60cm	6.5Fr*8cm	-	20Ga	5.5Fr	5mL	-	5mL	0.7mm	11#	Regular
CVMY35520	3-5.5Fr-20cm-Y	3-5.5Fr-20cm	0.021"*60cm	6.5Fr*8cm	20Ga	-	5.5Fr	5mL	5mL	-	0.7mm	11#	Regular

REF	Type specifications	Specification											
		Central Venous Catheter	Guide wire	Dilator	Introducer Needle		Fastener	Hypodermic Syringe		Blue introducer syringe	Hypodermic Needle	Scalpel	Injection site cap
					Y Model	I Model		I Model	II Model				
ICVM35520	3-5.5Fr-20cm-I	3-5.5Fr-20cm	0.021"*60cm	6.5Fr*8cm	-	20Ga	5.5Fr	5mL	-	5mL	0.7mm	11#	Regular
CVMY37016	3-7Fr-16cm-Y	3-7Fr-16cm	0.035"*60cm	8.5Fr*10cm	18Ga	-	7Fr	5mL	5mL	-	0.7mm	11#	Regular
ICVM37016	3-7Fr-16cm-I	3-7Fr-16cm	0.035"*60cm	8.5Fr*10cm	-	18Ga	7Fr	5mL	-	5mL	0.7mm	11#	Regular
CVMY37020	3-7Fr-20cm-Y	3-7Fr-20cm	0.035"*60cm	8.5Fr*10cm	18Ga	-	7Fr	5mL	5mL	-	0.7mm	11#	Regular
ICVM37020	3-7Fr-20cm-I	3-7Fr-20cm	0.035"*60cm	8.5Fr*10cm	-	18Ga	7Fr	5mL	-	5mL	0.7mm	11#	Regular
CVMY37030	3-7Fr-30cm-Y	3-7Fr-30cm	0.035"*60cm	8.5Fr*10cm	18Ga	-	7Fr	5mL	5mL	-	0.7mm	11#	Regular
ICVM37030	3-7Fr-30cm-I	3-7Fr-30cm	0.035"*60cm	8.5Fr*10cm	-	18Ga	7Fr	5mL	-	5mL	0.7mm	11#	Regular
CVMY38516	3-8.5Fr-16cm-Y	3-8.5Fr-16cm	0.035"*60cm	9Fr*10cm	18Ga	-	8.5Fr	5mL	5mL	-	0.7mm	11#	Regular
ICVM38516	3-8.5Fr-16cm-I	3-8.5Fr-16cm	0.035"*60cm	9Fr*10cm	-	18Ga	8.5Fr	5mL	-	5mL	0.7mm	11#	Regular
CVMY38520	3-8.5Fr-20cm-Y	3-8.5Fr-20cm	0.035"*60cm	9Fr*10cm	18Ga	-	8.5Fr	5mL	5mL	-	0.7mm	11#	Regular
ICVM38520	3-8.5Fr-20cm-I	3-8.5Fr-20cm	0.035"*60cm	9Fr*10cm	-	18Ga	8.5Fr	5mL	-	5mL	0.7mm	11#	Regular
CVMY38530	3-8.5Fr-30cm-Y	3-8.5Fr-30cm	0.035"*60cm	9Fr*10cm	18Ga	-	8.5Fr	5mL	5mL	-	0.7mm	11#	Regular
ICVM38530	3-8.5Fr-30cm-I	3-8.5Fr-30cm	0.035"*60cm	9Fr*10cm	-	18Ga	8.5Fr	5mL	-	5mL	0.7mm	11#	Regular
CVMY48520	4-8.5Fr-20cm-Y	4-8.5Fr-20cm	0.035"*60cm	9Fr*10cm	18Ga	-	8.5Fr	5mL	5mL	-	0.7mm	11#	Regular
ICVM48520	4-8.5Fr-20cm-I	4-8.5Fr-20cm	0.035"*60cm	9Fr*10cm	-	18Ga	8.5Fr	5mL	-	5mL	0.7mm	11#	Regular
CVMY48530	4-8.5Fr-30cm-Y	4-8.5Fr-30cm	0.035"*60cm	9Fr*10cm	18Ga	-	8.5Fr	5mL	5mL	-	0.7mm	11#	Regular
ICVM48530	4-8.5Fr-30cm-I	4-8.5Fr-30cm	0.035"*60cm	9Fr*10cm	-	18Ga	8.5Fr	5mL	-	5mL	0.7mm	11#	Regular

Accessories: This product has no accessories.

Annex 2 Applied Standards/Common Specifications (CS) List

The standards/Common Specifications (CS) applicable for this product are listed as below:

Standard and common specifications	Description	Date of issue	Full Compliance /Partial Compliance
EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices	2013-09-25	Full
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	2016-11-30	Full
EN ISO 14971:2019	Medical devices – Application of risk management to medical devices	2019-12-18	Full
EN ISO 13485:2016+AC:2018	Medical devices - Quality management systems - Requirements for regulatory purposes	2018-03-28	Partial Compliance
EN ISO14155:2020	Clinical investigation of medical devices for human subjects - Good clinical practice	2020-08-19	Full
MEDDEV 2.7/1 rev.4	CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES UNDER DIRECTIVES 93/42/EEC and 90/385/EEC	2016-06	Full
MEDDEV 2.12/1 rev.8	GUIDELINES ON A MEDICAL DEVICES VIGILANCE SYSTEM	2013-01	Full
ASTM D4169-16	Standard Practice for Performance Testing of Shipping Containers and Systems	2016-04-01	Full
EN ISO 10555-1:2013/A1:2017	Sterile, single-use intravascular catheters - Part1: General requirements	2017-12-20	Full
EN ISO 10555- 3:2013	Sterile, single-use intravascular catheters - Part3: Central venous catheters	2013-07-10	Full
EN ISO 80369-7:2017	Small-bore connectors for liquids and gases in healthcare applications. Part 7: Connectors for intravascular or hypodermic applications	2017-05-31	Full
EN ISO 11070:2014/AMD1:2018	Sterile single-use intravascular catheter introducers	2018-07-04	Full
EN ISO 7886-1:2018	Sterile hypodermic syringes for single use - Part 1: Syringes for manual use	2018-03-28	Full
EN ISO 7864: 2016	Sterile hypodermic needles for single use — Requirements and test methods	2016-08-31	Full
EN ISO 9626: 2016	Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods	2016-08-31	Full
YY0581.1-2011	Infusion access adapters-Part 1: Needle access adapters(Heparin plugs)	2011-12-31	Full
YY/T0454-2008	Disposable scalpel	2008-10-17	Full
EN ISO 11607-1:2020	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems	2020-01-15	Full
EN ISO 11607-2:2020	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes	2020-01-15	Full
EN 868.5:2018	Packaging for terminally sterilized medical devices-Part 5: Sealable pouches and reels of porous materials and plastic film construction-Requirements and test method.	2018	Full
EN ISO 11135: 2014/A1: 2019	Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices	2019-11-20	Full

Standard and common specifications	Description	Date of issue	Full Compliance /Partial Compliance
EN ISO 11737-1:2018	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	2018-01-31	Full
EN ISO 11737-2:2020	Sterilization of healthcare products - Radiation - Part 2: Establishing the sterilization dose	2020-05-13	Full
EN ISO 10993-1:2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	2020-12-16	Full
EN ISO 10993-3:2014	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	2014-10-15	Full
EN ISO 10993-4:2017	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood	2017-10-18	Full
EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	2009-06-01	Full
EN ISO 10993-6:2016	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation	2016-12-14	Full
EN ISO 10993-10:2013	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	2013-08-21	Full
EN ISO 10993-11:2018	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity	2018-05-30	Full
EN ISO 10993-12:2012	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials	2012-07-01	Full
EN ISO 10993-18:2020	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process	2020-05-27	Full