

Agenția Medicamentului
și Dispozitivelor Medicale

NOTIFICARE

pentru înregistrarea dispozitivelor medicale în Registrul de stat al dispozitivelor medicale

nr. 59 din 15.09.2023

Solicitantul **FPC "SOGNO" S.R.L.**, cu sediul MD-2028, mun.Chișinău, str.Academiei, 2, tel.:(022) 72-75-25/ 069501992, fax:(022) 73-83-42, e-mail: sognomd@gmail.com,
solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii și tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

Conform Anexei nr.3 "Lista dispozitivelor medicale Henan Tuoren Best Medical Device Co., Ltd."

Se anexează următoarele acte:

1. Certificat CE,
2. Declarație de Conformitate,
3. Scrisoarea autorizată a producătorului,
4. Declarație pe propria răspundere,
5. Lista dispozitivelor medicale.

Data: 15.09.2023


Semnătura _____

Tabelul de recepționare a notificării

(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAȚIE PE PROPRIE RĂSPUNDERE

Solicitant: **FPC "SOGNO" SRL**, cu sediul m.Chîșinău, str. Academiei nr.2, Republica Moldova,
declar pe proprie răspundere, cunoscând prevederile art. 352¹, Codul Penal al Republicii Moldova cu privire la
falsul în declarații, că documentele și datele furnizate pentru notificarea dispozitivelor medicale:

Conform Anexei nr.3 "Lista dispozitivelor medicale Henan Tuoren Best Medical Device Co., Ltd."

Sunt autentice și corespund realității.



Iarovoi Petru, Director

Semnătura

Data: 15.09.2023

Lista dispozitivelor medicale Henan Tuoren Best Medical Device Co., Ltd.

Numarul de catalog	Denumire	Denumirea comerciala	Modelul	Tip dispozitiv	Cod UDI-DI
ICVM37016	SET CATETER CU TREI LUMENE PENTRU CATETERIZARE VENE CENTRALE	—	3-7Fr-16cm-I	Dispozitiv invaziv	694242711359FE

Iarovoi Petru, Director

Semnătura



Henan Tuoren Best Medical Device Co., Ltd.

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

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

Website: <http://www.tuoren.com>

Letter of Authorization

We, Henan Tuoren Best Medical Device Co., Ltd. based in Middle of Weft 7 Road, Nanpu District, Changyuan, Henan, 453400, China, assign FPC "SOGNO" SRL, based at No 2 Academiei str., Chisinau, Republic of Moldova, as authorized representative in correspondence with the conditions of Regulation (EU) 2017/745.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

Place: Changyuan City

Date: 08.Sep.2023

Signature: _____



EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 734120 R000

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

Address:

Middle of Weft 7 Road
Nanpu District
Changyuan
Henan
453400
China

Single Registration Number: CN-MF-000007452

EU Authorised Representative: Lotus NL B.V.

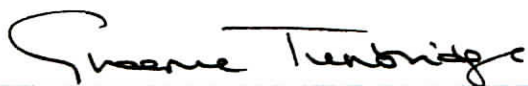
Address:

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

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

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



Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2021-07-01**

Current Issue Date: **2023-06-16**

Starting Validity Date: **2023-06-16**

Expiry Date: **2026-06-30**

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Page 1 of 3

Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as denoted through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V. - Sav Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 312 20 31
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 3AL
A Member of the BSI Group of Companies.



EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 734120 R000

Device Schedule: Class III and Class IIb devices

Class III

Central Venous Catheter (CVC) Kit

Intended purpose

See MDR 734121

Device Schedule: Class IIa, Custom-made and other devices

Device(s)

Surgical Face Mask

Risk Classification

Class Is

For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions.

First Issue Date: **2021-07-01**

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Expiry Date: **2026-06-30**

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A Member of the BSI Group of Companies.



EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 734121 R000

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

Address:

Middle of Weft 7 Road
Nanpu District
Changyuan
Henan
453400
China

Single Registration Number: CN-MF-000007452

EU Authorised Representative: Lotus NL B.V.

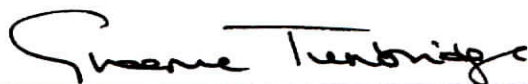
Address:

Koningin Julianaplein 10
1e Verd
2595AA The Hague
Netherlands

Scope: See attached **Device Schedule**

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/745, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III certificate is required.

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



Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2023-06-16**

Current Issue Date: **2023-06-16**

Starting Validity Date: **2023-06-16**

Expiry Date: **2028-06-15**

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EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 734121 R000

Device Schedule:

Device Name: Central Venous Catheter (CVC) Kit

Type (Codes as per (EU) 2017/2185): MDN 1202

Intended Purpose as per the Instructions for Use: Central Venous Catheter (CVC) Kit is used to insert into the central venous system for the infusions of fluids or medications, blood sampling or pressure measurement.

Risk Classification: Class III

Basic UDI-DI: 694242711359FE

Kits with extension line clamp 1.7#, no 5mL blue introducer syringe:

Model #	Description					
	Guidewire Diameter Length	Dilator Diameter Length	Introducer Needle	Fastener	Hypodermic Syringe (I model)	Hypodermic Syringe (II model)
1-22Ga-08cm-Y	0.018" 60cm	4Fr 5cm	20Ga	22Ga	5mL	5mL
1-22Ga-13cm-Y	0.018" 60cm	4Fr 5cm	20Ga	22Ga	5mL	5mL
1-22Ga-16cm-Y	0.018" 60cm	4Fr 5cm	20Ga	22Ga	5mL	5mL
1-22Ga-20cm-Y	0.018" 60cm	4Fr 5cm	20Ga	22Ga	5mL	5mL
1-22Ga-30cm-Y	0.018" 60cm	4Fr 5cm	20Ga	22Ga	5mL	5mL
1-20Ga-13cm-Y	0.021" 60cm	4Fr 5cm	20Ga	20Ga	5mL	5mL
1-20Ga-16cm-Y	0.021" 60cm	4Fr 5cm	20Ga	20Ga	5mL	5mL
1-20Ga-20cm-Y	0.021" 60cm	4Fr 5cm	20Ga	20Ga	5mL	5mL

First Issue Date: **2023-06-16**

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EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 734121 R000

Model #	Description					
	Guidewire Diameter Length	Dilator Diameter Length	Introducer Needle	Fastener	Hypodermic Syringe (I model)	Hypodermic Syringe (II model)
1-18Ga-13cm-Y	0.021" 60cm	5.5Fr 6cm	20Ga	18Ga	5mL	5mL
1-18Ga-16cm-Y	0.021" 60cm	5.5Fr 6cm	20Ga	18Ga	5mL	5mL
1-18Ga-20cm-Y	0.021" 60cm	5.5Fr 6cm	20Ga	18Ga	5mL	5mL
2-4Fr-05cm-Y	0.018" 60cm	5.5Fr 6cm	20Ga	18Ga	5mL	5mL
2-4Fr-08cm-Y	0.018" 60cm	5.5Fr 6cm	20Ga	18Ga	5mL	5mL
2-4Fr-13cm-Y	0.018" 60cm	5.5Fr 6cm	20Ga	18Ga	5mL	5mL
2-4Fr-16cm-Y	0.018" 60cm	5.5Fr 6cm	20Ga	18Ga	5mL	5mL
2-4Fr-20cm-Y	0.018" 60cm	5.5Fr 6cm	20Ga	18Ga	5mL	5mL
2-5Fr-13cm-Y	0.021" 60cm	5.5Fr 6cm	20Ga	16Ga	5mL	5mL
2-5Fr-16cm-Y	0.021" 60cm	5.5Fr 6cm	20Ga	16Ga	5mL	5mL
2-5Fr-20cm-Y	0.021" 60cm	5.5Fr 6cm	20Ga	16Ga	5mL	5mL
3-4Fr-08cm-Y	0.018" 60cm	5.5Fr 6cm	20Ga	18Ga	5mL	5mL
3-4Fr-13cm-Y	0.018" 60cm	5.5Fr 6cm	20Ga	18Ga	5mL	5mL
3-4Fr-16cm-Y	0.018" 60cm	5.5Fr 6cm	20Ga	18Ga	5mL	5mL

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EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 734121 R000

Model #	Description					
	Guidewire Diameter Length	Dilator Diameter Length	Introducer Needle	Fastener	Hypodermic Syringe (I model)	Hypodermic Syringe (II model)
3-4Fr-20cm-Y	0.018" 60cm	5.5Fr 6cm	20Ga	18Ga	5mL	5mL
3-5.5Fr-08cm-Y	0.021" 60cm	6.5Fr 8cm	20Ga	5.5Fr	5mL	5mL
3-5.5Fr-13cm-Y	0.021" 60cm	6.5Fr 8cm	20Ga	5.5Fr	5mL	5mL
3-5.5Fr-16cm-Y	0.021" 60cm	6.5Fr 8cm	20Ga	5.5Fr	5mL	5mL
3-5.5Fr-20cm-Y	0.021" 60cm	6.5Fr 8cm	20Ga	5.5Fr	5mL	5mL

Kits with extension line clamp 1.7# & 5mL blue introducer syringe:

Model #	Description					
	Guidewire	Dilator	Introducer Needle	Fastener	Hypodermic Syringe (I model)	Hypodermic Syringe (II model)
1-22Ga-08cm-I	0.018" 60cm	4Fr 5cm	20Ga	22Ga	5mL	-
1-22Ga-13cm-I	0.018" 60cm	4Fr 5cm	20Ga	22Ga	5mL	-
1-22Ga-16cm-I	0.018" 60cm	4Fr 5cm	20Ga	22Ga	5mL	-
1-22Ga-20cm-I	0.018" 60cm	4Fr 5cm	20Ga	22Ga	5mL	-
1-22Ga-30cm-I	0.018" 60cm	4Fr 5cm	20Ga	22Ga	5mL	-

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EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 734121 R000

Model #	Description					
	Guidewire	Dilator	Introducer Needle	Fastener	Hypodermic Syringe (I model)	Hypodermic Syringe (II model)
1-20Ga-13cm-I	0.021" 60cm	4Fr 5cm	20Ga	20Ga	5mL	-
1-20Ga-16cm-I	0.021" 60cm	4Fr 5cm	20Ga	20Ga	5mL	-
1-20Ga-20cm-I	0.021" 60cm	4Fr 5cm	20Ga	20Ga	5mL	-
1-18Ga-13cm-I	0.021" 60cm	5.5Fr 6cm	20Ga	18Ga	5mL	-
1-18Ga-16cm-I	0.021" 60cm	5.5Fr 6cm	20Ga	18Ga	5mL	-
1-18Ga-20cm-I	0.021" 60cm	5.5Fr 6cm	20Ga	18Ga	5mL	-
2-4Fr-05cm-I	0.018" 60cm	5.5Fr 6cm	20Ga	18Ga	5mL	-
2-4Fr-08cm-I	0.018" 60cm	5.5Fr 6cm	20Ga	18Ga	5mL	-
2-4Fr-13cm-I	0.018" 60cm	5.5Fr 6cm	20Ga	18Ga	5mL	-
2-4Fr-16cm-I	0.018" 60cm	5.5Fr 6cm	20Ga	18Ga	5mL	-
2-4Fr-20cm-I	0.018" 60cm	5.5Fr 6cm	20Ga	18Ga	5mL	-
2-5Fr-13cm-I	0.021" 60cm	5.5Fr 6cm	20Ga	16Ga	5mL	-
2-5Fr-16cm-I	0.021" 60cm	5.5Fr 6cm	20Ga	16Ga	5mL	-
2-5Fr-20cm-I	0.021" 60cm	5.5Fr 6cm	20Ga	16Ga	5mL	-

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EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 734121 R000

Model #	Description					
	Guidewire	Dilator	Introducer Needle	Fastener	Hypodermic Syringe (I model)	Hypodermic Syringe (II model)
3-4Fr-08cm-I	0.018" 60cm	5.5Fr 6cm	20Ga	18Ga	5mL	-
3-4Fr-13cm-I	0.018" 60cm	5.5Fr 6cm	20Ga	18Ga	5mL	-
3-4Fr-16cm-I	0.018" 60cm	5.5Fr 6cm	20Ga	18Ga	5mL	-
3-4Fr-20cm-I	0.018" 60cm	5.5Fr 6cm	20Ga	18Ga	5mL	-
3-5.5Fr-08cm-I	0.021" 60cm	6.5Fr 8cm	20Ga	5.5Fr	5mL	-
3-5.5Fr-13cm-I	0.021" 60cm	6.5Fr 8cm	20Ga	5.5Fr	5mL	-
3-5.5Fr-16cm-I	0.021" 60cm	6.5Fr 8cm	20Ga	5.5Fr	5mL	-
3-5.5Fr-20cm-I	0.021" 60cm	6.5Fr 8cm	20Ga	5.5Fr	5mL	-

Kits with extension line clamp 2.2#, no 5mL blue introducer syringe:

Model #	Description					
	Guidewire	Dilator	Introducer Needle	Fastener	Hypodermic Syringe (I model)	Hypodermic Syringe (II model)
1-16Ga-16cm-Y	0.035" 60cm	6.5Fr 10cm	18Ga	16Ga	5mL	5mL
1-16Ga-20cm-Y	0.035" 60cm	6.5Fr 10cm	18Ga	16Ga	5mL	5mL

First Issue Date: **2023-06-16**

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Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL
A Member of the BSI Group of Companies.



EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 734121 R000

Model #	Description					
	Guidewire	Dilator	Introducer Needle	Fastener	Hypodermic Syringe (I model)	Hypodermic Syringe (II model)
1-16Ga-30cm-Y	0.035" 60cm	6.5Fr 10cm	18Ga	16Ga	5mL	5mL
2-6Fr-13cm-Y	0.021" 60cm	6.5Fr 8cm	20Ga	5.5Fr	5mL	5mL
2-6Fr-16cm-Y	0.021" 60cm	6.5Fr 8cm	20Ga	5.5Fr	5mL	5mL
2-6Fr-20cm-Y	0.021" 60cm	6.5Fr 8cm	20Ga	5.5Fr	5mL	5mL
2-7Fr-16cm-Y	0.035" 60cm	8.5Fr 10cm	18Ga	7Fr	5mL	5mL
2-7Fr-20cm-Y	0.035" 60cm	8.5Fr 10cm	18Ga	7Fr	5mL	5mL
2-7Fr-30cm-Y	0.035" 60cm	8.5Fr 10cm	18Ga	7Fr	5mL	5mL
3-7Fr-16cm-Y	0.035" 60cm	8.5Fr 10cm	18Ga	7Fr	5mL	5mL
3-7Fr-20cm-Y	0.035" 60cm	8.5Fr 10cm	18Ga	7Fr	5mL	5mL
3-7Fr-30cm-Y	0.035" 60cm	8.5Fr 10cm	18Ga	7Fr	5mL	5mL
4-8.5Fr-20cm-Y	0.035" 60cm	9Fr 10cm	18Ga	8.5Fr	5mL	5mL
4-8.5Fr-30cm-Y	0.035" 60cm	9Fr 10cm	18Ga	8.5Fr	5mL	5mL

First Issue Date: **2023-06-16**

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EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 734121 R000

Kits with extension line clamp 2.2# & 5mL blue introducer syringe:

Model #	Description					
	Guidewire	Dilator	Introducer Needle	Fastener	Hypodermic Syringe (I model)	Hypodermic Syringe (II model)
1-16Ga-16cm-I	0.035" 60cm	6.5Fr 10cm	18Ga	16Ga	5mL	-
1-16Ga-20cm-I	0.035" 60cm	6.5Fr 10cm	18Ga	16Ga	5mL	-
1-16Ga-30cm-I	0.035" 60cm	6.5Fr 10cm	18Ga	16Ga	5mL	-
2-6Fr-13cm-I	0.021" 60cm	6.5Fr 8cm	20Ga	5.5Fr	5mL	-
2-6Fr-16cm-I	0.021" 60cm	6.5Fr 8cm	20Ga	5.5Fr	5mL	-
2-6Fr-20cm-I	0.021" 60cm	6.5Fr 8cm	20Ga	5.5Fr	5mL	-
2-7Fr-16cm-I	0.035" 60cm	8.5Fr 10cm	18Ga	7Fr	5mL	-
2-7Fr-20cm-I	0.035" 60cm	8.5Fr 10cm	18Ga	7Fr	5mL	-
2-7Fr-30cm-I	0.035" 60cm	8.5Fr 10cm	18Ga	7Fr	5mL	-
3-7Fr-16cm-I	0.035" 60cm	8.5Fr 10cm	18Ga	7Fr	5mL	-
3-7Fr-20cm-I	0.035" 60cm	8.5Fr 10cm	18Ga	7Fr	5mL	-
3-7Fr-30cm-I	0.035" 60cm	8.5Fr 10cm	18Ga	7Fr	5mL	-
4-8.5Fr-20cm-I	0.035" 60cm	9Fr 10cm	18Ga	8.5Fr	5mL	-

First Issue Date: **2023-06-16**

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EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 734121 R000

Model #	Description					
	Guidewire	Dilator	Introducer Needle	Fastener	Hypodermic Syringe (I model)	Hypodermic Syringe (II model)
4-8.5Fr-30cm-I	0.035" 60cm	9Fr 10cm	18Ga	8.5Fr	5mL	-

Kits with extension line clamp 2.5#, no 5mL blue introducer syringe:

Model #	Description					
	Guidewire	Dilator	Introducer Needle	Fastener	Hypodermic Syringe (I model)	Hypodermic Syringe (II model)
1-14Ga-16cm-Y	0.035" 60cm	8Fr 10cm	18Ga	14Ga	5mL	5mL
1-14Ga-20cm-Y	0.035" 60cm	8Fr 10cm	18Ga	14Ga	5mL	5mL
1-14Ga-30cm-Y	0.035" 60cm	8Fr 10cm	18Ga	14Ga	5mL	5mL
2-8Fr-16cm-Y	0.035" 60cm	8.5Fr 10cm	18Ga	8.5Fr	5mL	5mL
2-8Fr-20cm-Y	0.035" 60cm	8.5Fr 10cm	18Ga	8.5Fr	5mL	5mL
2-8Fr-30cm-Y	0.035" 60cm	8.5Fr 10cm	18Ga	8.5Fr	5mL	5mL
3-8.5Fr-16cm-Y	0.035" 60cm	9Fr 10cm	18Ga	8.5Fr	5mL	5mL
3-8.5Fr-20cm-Y	0.035" 60cm	9Fr 10cm	18Ga	8.5Fr	5mL	5mL
3-8.5Fr-30cm-Y	0.035" 60cm	9Fr 10cm	18Ga	8.5Fr	5mL	5mL

First Issue Date: **2023-06-16**

Current Issue Date: **2023-06-16**

Starting Validity Date: **2023-06-16**

Expiry Date: **2028-06-15**

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Page 9 of 12

Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK
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EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 734121 R000

Kits with extension line clamp 2.5# & 5mL blue introducer syringe:

Model #	Description					
	Guidewire	Dilator	Introducer Needle	Fastener	Hypodermic Syringe (I model)	Hypodermic Syringe (II model)
1-14Ga-16cm-I	0.035" 60cm	8Fr 10cm	18Ga	14Ga	5mL	-
1-14Ga-20cm-I	0.035" 60cm	8Fr 10cm	18Ga	14Ga	5mL	-
1-14Ga-30cm-I	0.035" 60cm	8Fr 10cm	18Ga	14Ga	5mL	-
2-8Fr-16cm-I	0.035" 60cm	8.5Fr 10cm	18Ga	8.5Fr	5mL	-
2-8Fr-20cm-I	0.035" 60cm	8.5Fr 10cm	18Ga	8.5Fr	5mL	-
2-8Fr-30cm-I	0.035" 60cm	8.5Fr 10cm	18Ga	8.5Fr	5mL	-
3-8.5Fr-16cm-I	0.035" 60cm	9Fr 10cm	18Ga	8.5Fr	5mL	-
3-8.5Fr-20cm-I	0.035" 60cm	9Fr 10cm	18Ga	8.5Fr	5mL	-
3-8.5Fr-30cm-I	0.035" 60cm	9Fr 10cm	18Ga	8.5Fr	5mL	-

Kits with extension line clamp 3.0#, no 5mL blue introducer syringe:

Model #	Description					
	Guidewire	Dilator	Introducer Needle	Fastener	Hypodermic Syringe (I model)	Hypodermic Syringe (II model)
1-12Ga-16cm-Y	0.035" 60cm	8.5Fr 10cm	18Ga	8.5Fr	5mL	5mL

First Issue Date: **2023-06-16**

Current Issue Date: **2023-06-16**

Starting Validity Date: **2023-06-16**

Expiry Date: **2028-06-15**

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Page 10 of 12

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EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 734121 R000

Model #	Description					
	Guidewire	Dilator	Introducer Needle	Fastener	Hypodermic Syringe (I model)	Hypodermic Syringe (II model)
1-12Ga-20cm-Y	0.035" 60cm	8.5Fr 10cm	18Ga	8.5Fr	5mL	5mL
1-12Ga-30cm-Y	0.035" 60cm	8.5Fr 10cm	18Ga	8.5Fr	5mL	5mL

Kits with extension line clamp 3.0# & 5mL blue introducer syringe:

Model #	Description					
	Guidewire	Dilator	Introducer Needle	Fastener	Hypodermic Syringe (I model)	Hypodermic Syringe (II model)
1-12Ga-16cm-I	0.035" 60cm	8.5Fr 10cm	18Ga	8.5Fr	5mL	-
1-12Ga-20cm-I	0.035" 60cm	8.5Fr 10cm	18Ga	8.5Fr	5mL	-
1-12Ga-30cm-I	0.035" 60cm	8.5Fr 10cm	18Ga	8.5Fr	5mL	-

Additional Information:

Model Description: (1)-(2)Ga/Fr-(3)cm-(4), where

- (1) Number of catheter lumens
- (2) Catheter diameter
- (3) Effective length of catheter
- (4) Introducer needle model (I or Y)

All kits include a 0.7mm hypodermic needle, a scalpel and an injection site cap.

First Issue Date: **2023-06-16**

Current Issue Date: **2023-06-16**

Starting Validity Date: **2023-06-16**

Expiry Date: **2028-06-15**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
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NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80.
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W9 4AL, UK.
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EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 734121 R000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	3271198	Issued.

First Issue Date: **2023-06-16**

Current Issue Date: **2023-06-16**

Starting Validity Date: **2023-06-16**

Expiry Date: **2028-06-15**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 3AL
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EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 734120 R000

Certificate History

Date	Reference Number	Action
2021-07-01	3271197	Issued
2023-03-22	3873068	Restricted – Removal of Disposable Medical Isolation Gown, Disposable Medical Protective Coverall, Medical Silicone Mask, Medical Protective Hood. Amended – Addition of subcontractors for manufacturing and sterility test of Surgical Face Mask.
Current	30000902	Supplemented – Addition of Central Venous Catheter (CVC) Kit

First Issue Date: **2021-07-01**

Current Issue Date: **2023-06-16**

Starting Validity Date: **2023-06-16**

Expiry Date: **2026-06-30**

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Page 3 of 3

Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as the result of the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands, Tel: + 31 (0) 20 7619 7000
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W9 1AL, UK.
A Member of the BSI Group of Companies.



EU Declaration of Conformity

(Document No.: BST-CE-06-02)

——Central Venous Catheter (CVC) Kit

REVISION STATUS:

Version	Brief Description of Revision	Author	Date
A0	Initial revision	Shi Wenping	2023-06-17



段端

Henan Tuoren Best Medical Device Co., Ltd.

EU Declaration of Conformity

Manufacturer: Henan Tuoren Best Medical Device Co., Ltd.
Address: Middle of Weft 7 Road, Nanpu District, Changyuan, Henan, 453400, China
Tel: +86 0373-8814000 **Fax:** +86 0373-8816222
Website: <http://www.tuoren.com/>
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
Intended use: Central Venous Catheter (CVC) Kit is used to insert into the central venous system for the infusions of fluids or medications, blood sampling or pressure measurement.

Basic UDI-DI: 694242711359FE
Model List: See Annex 1
Applicable Common Specification: N/A

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

Conformity Assessment Route: Annex IX Quality Management System and Chapter II Technical Documentation Assessment of the Regulation (EU) 2017/745(MDR).

We herewith declare that the above mentioned product meet the provisions of the Regulation (EU) 2017/745 (MDR) for medical devices.

Notified Body: BSI Group The Netherlands B.V.
Address: Say Building, John M.Keynesplein 9, 1066 EP, Amsterdam, Netherlands.
Tel: +31(0)203460780

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CE Technical file of Central Venous Catheter (CVC) Kit
— EU Declaration of Conformity
File No.: BST-CE-06-02
Revision: A0
Effective Date: 2023-06-17

Notified Body Number:

CE 2797

Certificate	Initially issued	Last renewal	Valid until
Full Quality Assurance Certificate - Annex IX Chapter I and III Certificate No.: MDR 734120	2021-07-01	2023-06-16	2026-06-30
EU-Technical Documentation Assessment - Annex IX Chapter II Certificate NO.: MDR 734121	2023-06-16	/	2028-06-15

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:

Li Ruilei

Name

: Li Ruilei

Function (Company)

: Management Representative

Date

: 2023.6.17 YYYY/MM/DD

Location

: Henan



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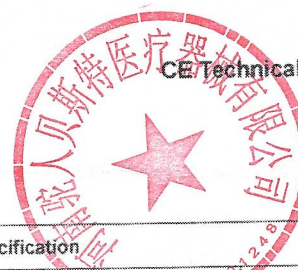


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Annex 1 Model List

Product Code	Catalogue Number	Specification												
		Central Venous Catheter	Guide wire	Dilator	Introducer Needle		Fastener	Hypodermic Syringe		Blue introducer syringe	Hypodermic Needle	Scalp el	Injection site cap	Extensi on line clamp
					Y Model	I Model		I Model	II Model					
CVMY12208	1-22Ga-08cm-Y	1-22Ga-08cm	0.018"*60cm	4Fr*5cm	20Ga	-	22Ga	5mL	5mL	-	0.7mm	11#	Regular	1.7#
ICVM12208	1-22Ga-08cm-I	1-22Ga-08cm	0.018"*60cm	4Fr*5cm	-	20Ga	22Ga	5mL	-	5mL	0.7mm	11#	Regular	1.7#
CVMY12213	1-22Ga-13cm-Y	1-22Ga-13cm	0.018"*60cm	4Fr*5cm	20Ga	-	22Ga	5mL	5mL	-	0.7mm	11#	Regular	1.7#
ICVM12213	1-22Ga-13cm-I	1-22Ga-13cm	0.018"*60cm	4Fr*5cm	-	20Ga	22Ga	5mL	-	5mL	0.7mm	11#	Regular	1.7#
CVMY12216	1-22Ga-16cm-Y	1-22Ga-16cm	0.018"*60cm	4Fr*5cm	20Ga	-	22Ga	5mL	5mL	-	0.7mm	11#	Regular	1.7#
ICVM12216	1-22Ga-16cm-I	1-22Ga-16cm	0.018"*60cm	4Fr*5cm	-	20Ga	22Ga	5mL	-	5mL	0.7mm	11#	Regular	1.7#
CVMY12220	1-22Ga-20cm-Y	1-22Ga-20cm	0.018"*60cm	4Fr*5cm	20Ga	-	22Ga	5mL	5mL	-	0.7mm	11#	Regular	1.7#
ICVM12220	1-22Ga-20cm-I	1-22Ga-20cm	0.018"*60cm	4Fr*5cm	-	20Ga	22Ga	5mL	-	5mL	0.7mm	11#	Regular	1.7#
CVMY12230	1-22Ga-30cm-Y	1-22Ga-30cm	0.018"*60cm	4Fr*5cm	20Ga	-	22Ga	5mL	5mL	-	0.7mm	11#	Regular	1.7#
ICVM12230	1-22Ga-30cm-I	1-22Ga-30cm	0.018"*60cm	4Fr*5cm	-	20Ga	22Ga	5mL	-	5mL	0.7mm	11#	Regular	1.7#
CVMY12013	1-20Ga-13cm-Y	1-20Ga-13cm	0.021"*60cm	4Fr*5cm	20Ga	-	20Ga	5mL	5mL	-	0.7mm	11#	Regular	1.7#
ICVM12013	1-20Ga-13cm-I	1-20Ga-13cm	0.021"*60cm	4Fr*5cm	-	20Ga	20Ga	5mL	-	5mL	0.7mm	11#	Regular	1.7#
CVMY12016	1-20Ga-16cm-Y	1-20Ga-16cm	0.021"*60cm	4Fr*5cm	20Ga	-	20Ga	5mL	5mL	-	0.7mm	11#	Regular	1.7#
ICVM12016	1-20Ga-16cm-I	1-20Ga-16cm	0.021"*60cm	4Fr*5cm	-	20Ga	20Ga	5mL	-	5mL	0.7mm	11#	Regular	1.7#
CVMY12020	1-20Ga-20cm-Y	1-20Ga-20cm	0.021"*60cm	4Fr*5cm	20Ga	-	20Ga	5mL	5mL	-	0.7mm	11#	Regular	1.7#
ICVM12020	1-20Ga-20cm-I	1-20Ga-20cm	0.021"*60cm	4Fr*5cm	-	20Ga	20Ga	5mL	-	5mL	0.7mm	11#	Regular	1.7#
CVMY11813	1-18Ga-13cm-Y	1-18Ga-13cm	0.021"*60cm	5.5Fr*6cm	20Ga	-	18Ga	5mL	5mL	-	0.7mm	11#	Regular	1.7#
ICVM11813	1-18Ga-13cm-I	1-18Ga-13cm	0.021"*60cm	5.5Fr*6cm	-	20Ga	18Ga	5mL	-	5mL	0.7mm	11#	Regular	1.7#
CVMY11816	1-18Ga-16cm-Y	1-18Ga-16cm	0.021"*60cm	5.5Fr*6cm	20Ga	-	18Ga	5mL	5mL	-	0.7mm	11#	Regular	1.7#
ICVM11816	1-18Ga-16cm-I	1-18Ga-16cm	0.021"*60cm	5.5Fr*6cm	-	20Ga	18Ga	5mL	-	5mL	0.7mm	11#	Regular	1.7#
CVMY11820	1-18Ga-20cm-Y	1-18Ga-20cm	0.021"*60cm	5.5Fr*6cm	20Ga	-	18Ga	5mL	5mL	-	0.7mm	11#	Regular	1.7#

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CE Technical file of Central Venous Catheter (CVC) Kit

— EU Declaration of Conformity

File No.: BST-CE-06-02

Revision: A0

Effective Date: 2023-06-17

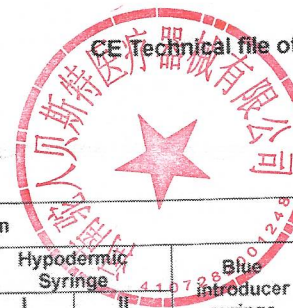
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Product Code	Catalogue Number	Specification												
		Central Venous Catheter	Guide wire	Dilator	Introducer Needle		Fastener	Hypodermic Syringe		Blue introducer syringe	Hypodermic Needle	Scalp el	Injection site cap	Extensi on line clamp
					Y Model	I Model		I Model	II Model					
ICVM11820	1-18Ga-20cm-I	1-18Ga-20cm	0.021"*60cm	5.5Fr*6cm	-	20Ga	18Ga	5mL	-	5mL	0.7mm	11#	Regular	1.7#
CVMY11616	1-16Ga-16cm-Y	1-16Ga-16cm	0.035"*60cm	6.5Fr*10cm	18Ga	-	16Ga	5mL	5mL	-	0.7mm	11#	Regular	2.2#
ICVM11616	1-16Ga-16cm-I	1-16Ga-16cm	0.035"*60cm	6.5Fr*10cm	-	18Ga	16Ga	5mL	-	5mL	0.7mm	11#	Regular	2.2#
CVMY11620	1-16Ga-20cm-Y	1-16Ga-20cm	0.035"*60cm	6.5Fr*10cm	18Ga	-	16Ga	5mL	5mL	-	0.7mm	11#	Regular	2.2#
ICVM11620	1-16Ga-20cm-I	1-16Ga-20cm	0.035"*60cm	6.5Fr*10cm	-	18Ga	16Ga	5mL	-	5mL	0.7mm	11#	Regular	2.2#
CVMY11630	1-16Ga-30cm-Y	1-16Ga-30cm	0.035"*60cm	6.5Fr*10cm	18Ga	-	16Ga	5mL	5mL	-	0.7mm	11#	Regular	2.2#
ICVM11630	1-16Ga-30cm-I	1-16Ga-30cm	0.035"*60cm	6.5Fr*10cm	-	18Ga	16Ga	5mL	-	5mL	0.7mm	11#	Regular	2.2#
CVMY11416	1-14Ga-16cm-Y	1-14Ga-16cm	0.035"*60cm	8Fr*10cm	18Ga	-	14Ga	5mL	5mL	-	0.7mm	11#	Regular	2.5#
ICVM11416	1-14Ga-16cm-I	1-14Ga-16cm	0.035"*60cm	8Fr*10cm	-	18Ga	14Ga	5mL	-	5mL	0.7mm	11#	Regular	2.5#
CVMY11420	1-14Ga-20cm-Y	1-14Ga-20cm	0.035"*60cm	8Fr*10cm	18Ga	-	14Ga	5mL	5mL	-	0.7mm	11#	Regular	2.5#
ICVM11420	1-14Ga-20cm-I	1-14Ga-20cm	0.035"*60cm	8Fr*10cm	-	18Ga	14Ga	5mL	-	5mL	0.7mm	11#	Regular	2.5#
CVMY11430	1-14Ga-30cm-Y	1-14Ga-30cm	0.035"*60cm	8Fr*10cm	18Ga	-	14Ga	5mL	5mL	-	0.7mm	11#	Regular	2.5#
ICVM11430	1-14Ga-30cm-I	1-14Ga-30cm	0.035"*60cm	8Fr*10cm	-	18Ga	14Ga	5mL	-	5mL	0.7mm	11#	Regular	2.5#
CVMY11216	1-12Ga-16cm-Y	1-12Ga-16cm	0.035"*60cm	8.5Fr*10cm	18Ga	-	8.5Fr	5mL	5mL	-	0.7mm	11#	Regular	3.0#
ICVM11216	1-12Ga-16cm-I	1-12Ga-16cm	0.035"*60cm	8.5Fr*10cm	-	18Ga	8.5Fr	5mL	-	5mL	0.7mm	11#	Regular	3.0#
CVMY11220	1-12Ga-20cm-Y	1-12Ga-20cm	0.035"*60cm	8.5Fr*10cm	18Ga	-	8.5Fr	5mL	5mL	-	0.7mm	11#	Regular	3.0#
ICVM11220	1-12Ga-20cm-I	1-12Ga-20cm	0.035"*60cm	8.5Fr*10cm	-	18Ga	8.5Fr	5mL	-	5mL	0.7mm	11#	Regular	3.0#
CVMY11230	1-12Ga-30cm-Y	1-12Ga-30cm	0.035"*60cm	8.5Fr*10cm	18Ga	-	8.5Fr	5mL	5mL	-	0.7mm	11#	Regular	3.0#
ICVM11230	1-12Ga-30cm-I	1-12Ga-30cm	0.035"*60cm	8.5Fr*10cm	-	18Ga	8.5Fr	5mL	-	5mL	0.7mm	11#	Regular	3.0#
CVMY24005	2-4Fr-05cm-Y	2-4Fr-05cm	0.018"*60cm	5.5Fr*6cm	20Ga	-	18Ga	5mL	5mL	-	0.7mm	11#	Regular	1.7#
ICVM24005	2-4Fr-05cm-I	2-4Fr-05cm	0.018"*60cm	5.5Fr*6cm	-	20Ga	18Ga	5mL	-	5mL	0.7mm	11#	Regular	1.7#
CVMY24008	2-4Fr-08cm-Y	2-4Fr-08cm	0.018"*60cm	5.5Fr*6cm	20Ga	-	18Ga	5mL	5mL	-	0.7mm	11#	Regular	1.7#
ICVM24008	2-4Fr-08cm-I	2-4Fr-08cm	0.018"*60cm	5.5Fr*6cm	-	20Ga	18Ga	5mL	-	5mL	0.7mm	11#	Regular	1.7#



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Product Code	Catalogue Number	Specification												
		Central Venous Catheter	Guide wire	Dilator	Introducer Needle		Fastener	Hypodermic Syringe		Blue introducer syringe	Hypodermic Needle	Scalp el	Injection site cap	Extensi on line clamp
					Y Model	I Model		I Model	II Model					
CVMY24013	2-4Fr-13cm-Y	2-4Fr-13cm	0.018"*60cm	5.5Fr*6cm	20Ga	-	18Ga	5mL	5mL	-	0.7mm	11#	Regular	1.7#
ICVM24013	2-4Fr-13cm-I	2-4Fr-13cm	0.018"*60cm	5.5Fr*6cm	-	20Ga	18Ga	5mL	-	5mL	0.7mm	11#	Regular	1.7#
CVMY24016	2-4Fr-16cm-Y	2-4Fr-16cm	0.018"*60cm	5.5Fr*6cm	20Ga	-	18Ga	5mL	5mL	-	0.7mm	11#	Regular	1.7#
ICVM24016	2-4Fr-16cm-I	2-4Fr-16cm	0.018"*60cm	5.5Fr*6cm	-	20Ga	18Ga	5mL	-	5mL	0.7mm	11#	Regular	1.7#
CVMY24020	2-4Fr-20cm-Y	2-4Fr-20cm	0.018"*60cm	5.5Fr*6cm	20Ga	-	18Ga	5mL	5mL	-	0.7mm	11#	Regular	1.7#
ICVM24020	2-4Fr-20cm-I	2-4Fr-20cm	0.018"*60cm	5.5Fr*6cm	-	20Ga	18Ga	5mL	-	5mL	0.7mm	11#	Regular	1.7#
CVMY25013	2-5Fr-13cm-Y	2-5Fr-13cm	0.021"*60cm	5.5Fr*6cm	20Ga	-	16Ga	5mL	5mL	-	0.7mm	11#	Regular	1.7#
ICVM25013	2-5Fr-13cm-I	2-5Fr-13cm	0.021"*60cm	5.5Fr*6cm	-	20Ga	16Ga	5mL	-	5mL	0.7mm	11#	Regular	1.7#
CVMY25016	2-5Fr-16cm-Y	2-5Fr-16cm	0.021"*60cm	5.5Fr*6cm	20Ga	-	16Ga	5mL	5mL	-	0.7mm	11#	Regular	1.7#
ICVM25016	2-5Fr-16cm-I	2-5Fr-16cm	0.021"*60cm	5.5Fr*6cm	-	20Ga	16Ga	5mL	-	5mL	0.7mm	11#	Regular	1.7#
CVMY25020	2-5Fr-20cm-Y	2-5Fr-20cm	0.021"*60cm	5.5Fr*6cm	20Ga	-	16Ga	5mL	5mL	-	0.7mm	11#	Regular	1.7#
ICVM25020	2-5Fr-20cm-I	2-5Fr-20cm	0.021"*60cm	5.5Fr*6cm	-	20Ga	16Ga	5mL	-	5mL	0.7mm	11#	Regular	1.7#
CVMY26013	2-6Fr-13cm-Y	2-6Fr-13cm	0.021"*60cm	6.5Fr*8cm	20Ga	-	5.5Fr	5mL	5mL	-	0.7mm	11#	Regular	2.2#
ICVM26013	2-6Fr-13cm-I	2-6Fr-13cm	0.021"*60cm	6.5Fr*8cm	-	20Ga	5.5Fr	5mL	-	5mL	0.7mm	11#	Regular	2.2#
CVMY26016	2-6Fr-16cm-Y	2-6Fr-16cm	0.021"*60cm	6.5Fr*8cm	20Ga	-	5.5Fr	5mL	5mL	-	0.7mm	11#	Regular	2.2#
ICVM26016	2-6Fr-16cm-I	2-6Fr-16cm	0.021"*60cm	6.5Fr*8cm	-	20Ga	5.5Fr	5mL	-	5mL	0.7mm	11#	Regular	2.2#
CVMY26020	2-6Fr-20cm-Y	2-6Fr-20cm	0.021"*60cm	6.5Fr*8cm	20Ga	-	5.5Fr	5mL	5mL	-	0.7mm	11#	Regular	2.2#
ICVM26020	2-6Fr-20cm-I	2-6Fr-20cm	0.021"*60cm	6.5Fr*8cm	-	20Ga	5.5Fr	5mL	-	5mL	0.7mm	11#	Regular	2.2#
CVMY27016	2-7Fr-16cm-Y	2-7Fr-16cm	0.035"*60cm	8.5Fr*10cm	18Ga	-	7Fr	5mL	5mL	-	0.7mm	11#	Regular	2.2#
ICVM27016	2-7Fr-16cm-I	2-7Fr-16cm	0.035"*60cm	8.5Fr*10cm	-	18Ga	7Fr	5mL	-	5mL	0.7mm	11#	Regular	2.2#
CVMY27020	2-7Fr-20cm-Y	2-7Fr-20cm	0.035"*60cm	8.5Fr*10cm	18Ga	-	7Fr	5mL	5mL	-	0.7mm	11#	Regular	2.2#
ICVM27020	2-7Fr-20cm-I	2-7Fr-20cm	0.035"*60cm	8.5Fr*10cm	-	18Ga	7Fr	5mL	-	5mL	0.7mm	11#	Regular	2.2#
CVMY27030	2-7Fr-30cm-Y	2-7Fr-30cm	0.035"*60cm	8.5Fr*10cm	18Ga	-	7Fr	5mL	5mL	-	0.7mm	11#	Regular	2.2#



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Product Code	Catalogue Number	Specification												
		Central Venous Catheter	Guide wire	Dilator	Introducer Needle		Fastener	Hypodermic Syringe		Blue introducer syringe	Hypodermic Needle	Scalp el	Injection site cap	Extensi on line clamp
					Y Model	I Model		I Model	Model					
ICVM27030	2-7Fr-30cm-I	2-7Fr-30cm	0.035"*60cm	8.5Fr*10cm	-	18Ga	7Fr	5mL	-	5mL	0.7mm	11#	Regular	2.2#
CVMY28016	2-8Fr-16cm-Y	2-8Fr-16cm	0.035"*60cm	8.5Fr*10cm	18Ga	-	8.5Fr	5mL	5mL	-	0.7mm	11#	Regular	2.5#
ICVM28016	2-8Fr-16cm-I	2-8Fr-16cm	0.035"*60cm	8.5Fr*10cm	-	18Ga	8.5Fr	5mL	-	5mL	0.7mm	11#	Regular	2.5#
CVMY28020	2-8Fr-20cm-Y	2-8Fr-20cm	0.035"*60cm	8.5Fr*10cm	18Ga	-	8.5Fr	5mL	5mL	-	0.7mm	11#	Regular	2.5#
ICVM28020	2-8Fr-20cm-I	2-8Fr-20cm	0.035"*60cm	8.5Fr*10cm	-	18Ga	8.5Fr	5mL	-	5mL	0.7mm	11#	Regular	2.5#
CVMY28030	2-8Fr-30cm-Y	2-8Fr-30cm	0.035"*60cm	8.5Fr*10cm	18Ga	-	8.5Fr	5mL	5mL	-	0.7mm	11#	Regular	2.5#
ICVM28030	2-8Fr-30cm-I	2-8Fr-30cm	0.035"*60cm	8.5Fr*10cm	-	18Ga	8.5Fr	5mL	-	5mL	0.7mm	11#	Regular	2.5#
CVMY34008	3-4Fr-08cm-Y	3-4Fr-08cm	0.018"*60cm	5.5Fr*6cm	20Ga	-	18Ga	5mL	5mL	-	0.7mm	11#	Regular	1.7#
ICVM34008	3-4Fr-08cm-I	3-4Fr-08cm	0.018"*60cm	5.5Fr*6cm	-	20Ga	18Ga	5mL	-	5mL	0.7mm	11#	Regular	1.7#
CVMY34013	3-4Fr-13cm-Y	3-4Fr-13cm	0.018"*60cm	5.5Fr*6cm	20Ga	-	18Ga	5mL	5mL	-	0.7mm	11#	Regular	1.7#
ICVM34013	3-4Fr-13cm-I	3-4Fr-13cm	0.018"*60cm	5.5Fr*6cm	-	20Ga	18Ga	5mL	-	5mL	0.7mm	11#	Regular	1.7#
CVMY34016	3-4Fr-16cm-Y	3-4Fr-16cm	0.018"*60cm	5.5Fr*6cm	20Ga	-	18Ga	5mL	5mL	-	0.7mm	11#	Regular	1.7#
ICVM34016	3-4Fr-16cm-I	3-4Fr-16cm	0.018"*60cm	5.5Fr*6cm	-	20Ga	18Ga	5mL	-	5mL	0.7mm	11#	Regular	1.7#
CVMY34020	3-4Fr-20cm-Y	3-4Fr-20cm	0.018"*60cm	5.5Fr*6cm	20Ga	-	18Ga	5mL	5mL	-	0.7mm	11#	Regular	1.7#
ICVM34020	3-4Fr-20cm-I	3-4Fr-20cm	0.018"*60cm	5.5Fr*6cm	-	20Ga	18Ga	5mL	-	5mL	0.7mm	11#	Regular	1.7#
CVMY35508	3-5.5Fr-08cm-Y	3-5.5Fr-08cm	0.021"*60cm	6.5Fr*8cm	20Ga	-	5.5Fr	5mL	5mL	-	0.7mm	11#	Regular	1.7#
ICVM35508	3-5.5Fr-08cm-I	3-5.5Fr-08cm	0.021"*60cm	6.5Fr*8cm	-	20Ga	5.5Fr	5mL	-	5mL	0.7mm	11#	Regular	1.7#
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	1.7#
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	1.7#
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	1.7#
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	1.7#
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	1.7#
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	1.7#

Product Code	Catalogue Number	Specification												
		Central Venous Catheter	Guide wire	Dilator	Introducer Needle		Fastener	Hypodermic Syringe		Blue introducer syringe	Hypodermic Needle	Scalp el	Injection site cap	Extensi on line clamp
					Y Model	I Model		I Model	II Model					
CVMY37016	3-7Fr-16cm-Y	3-7Fr-16cm	0.035**60cm	8.5Fr*10cm	18Ga	-	7Fr	5mL	5mL	-	0.7mm	11#	Regular	2.2#
ICVM37016	3-7Fr-16cm-I	3-7Fr-16cm	0.035**60cm	8.5Fr*10cm	-	18Ga	7Fr	5mL	-	5mL	0.7mm	11#	Regular	2.2#
CVMY37020	3-7Fr-20cm-Y	3-7Fr-20cm	0.035**60cm	8.5Fr*10cm	18Ga	-	7Fr	5mL	5mL	-	0.7mm	11#	Regular	2.2#
ICVM37020	3-7Fr-20cm-I	3-7Fr-20cm	0.035**60cm	8.5Fr*10cm	-	18Ga	7Fr	5mL	-	5mL	0.7mm	11#	Regular	2.2#
CVMY37030	3-7Fr-30cm-Y	3-7Fr-30cm	0.035**60cm	8.5Fr*10cm	18Ga	-	7Fr	5mL	5mL	-	0.7mm	11#	Regular	2.2#
ICVM37030	3-7Fr-30cm-I	3-7Fr-30cm	0.035**60cm	8.5Fr*10cm	-	18Ga	7Fr	5mL	-	5mL	0.7mm	11#	Regular	2.2#
CVMY38516	3-8.5Fr-16cm-Y	3-8.5Fr-16cm	0.035**60cm	9Fr*10cm	18Ga	-	8.5Fr	5mL	5mL	-	0.7mm	11#	Regular	2.5#
ICVM38516	3-8.5Fr-16cm-I	3-8.5Fr-16cm	0.035**60cm	9Fr*10cm	-	18Ga	8.5Fr	5mL	-	5mL	0.7mm	11#	Regular	2.5#
CVMY38520	3-8.5Fr-20cm-Y	3-8.5Fr-20cm	0.035**60cm	9Fr*10cm	18Ga	-	8.5Fr	5mL	5mL	-	0.7mm	11#	Regular	2.5#
ICVM38520	3-8.5Fr-20cm-I	3-8.5Fr-20cm	0.035**60cm	9Fr*10cm	-	18Ga	8.5Fr	5mL	-	5mL	0.7mm	11#	Regular	2.5#
CVMY38530	3-8.5Fr-30cm-Y	3-8.5Fr-30cm	0.035**60cm	9Fr*10cm	18Ga	-	8.5Fr	5mL	5mL	-	0.7mm	11#	Regular	2.5#
ICVM38530	3-8.5Fr-30cm-I	3-8.5Fr-30cm	0.035**60cm	9Fr*10cm	-	18Ga	8.5Fr	5mL	-	5mL	0.7mm	11#	Regular	2.5#
CVMY48520	4-8.5Fr-20cm-Y	4-8.5Fr-20cm	0.035**60cm	9Fr*10cm	18Ga	-	8.5Fr	5mL	5mL	-	0.7mm	11#	Regular	2.2#
ICVM48520	4-8.5Fr-20cm-I	4-8.5Fr-20cm	0.035**60cm	9Fr*10cm	-	18Ga	8.5Fr	5mL	-	5mL	0.7mm	11#	Regular	2.2#
CVMY48530	4-8.5Fr-30cm-Y	4-8.5Fr-30cm	0.035**60cm	9Fr*10cm	18Ga	-	8.5Fr	5mL	5mL	-	0.7mm	11#	Regular	2.2#
ICVM48530	4-8.5Fr-30cm-I	4-8.5Fr-30cm	0.035**60cm	9Fr*10cm	-	18Ga	8.5Fr	5mL	-	5mL	0.7mm	11#	Regular	2.2#
Remarks	The number of Injection site caps and Extension line clamps should be consistent with the number of lumens of the catheter.													

Accessories: ECG lead cable and Positive pressure needle free connector (optional)



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