3) Turn the main pump off and double clamp the venous line (5 cm apart) next to the venous inlet port. Clamp the arterial line.
4) Double clamp the pump line next to the reservoir (5 cm apart).
5) Disconnect all monitoring and sampling lines and the temperature probe.
6) Cut the pump line and the venous line in the section between the two clamps, leaving a sufficient length of tubing to allow connection to the new reservoir.
7) Remove the Inspire HVR from the bracket if sterile stand alone.
8) Place a new reservoir onto the bracket. Connect all lines (i.e. pump line to the reservoir outlet port, venous line to the reservoir inlet connector, ...) and temperature probe.
9) Add enough priming solution to the new Inspire HVR to allow extracorporeal circulation being resumed.

WARNING

In this phase, keep the venous and arterial lines clamped.

10) Remove clamp from pump line, from the venous and the arterial line and start the bypass again.
11) Regulate main blood flow and restore suction flow. Adjust gas flow rate as required.
12) Add more priming solution to the new Inspire HVR reservoir as required.
13) Verify all connections and secure with tie straps.
14) The blood contained in the replaced reservoir can be recovered by connecting its outlet line to one of the venous reservoir inlets and draining by gravity.

WARNING

Upon completion of this operation contact SORIN GROUP or an authorised representative to analyse the Inspire HVR considered defective.

Q. MEDICAL DEVICES FOR USE WITH INSPIRE HVR

CAUTION

The user should observe the warnings and cautions and follow instructions for use accompanying the device.

- The Inspire HVR may be used in combination with Inspire 6 M code 050700, Inspire 8 M code 050701, Inspire 6F M code 050702 and Inspire 8F M code 050703 oxygenators.
- A special common interface allows to achieve integrated sterile stand alone devices configuration. Matrix of fig.3 shows full range of available sterile stand alone integrated devices generated by the combination of Inspire HVR and Inspire 6 M, Inspire 8 M, Inspire 6F M and Inspire 8F M.
- The device may be used in combination with an adult or small adult oxygenator module.
- All tubing used to make the circuit connections must be of a diameter which is compatible with the dimensions of the connectors on the device (1/2",3/8",1/4").
- Inspire BKTH bracket code 050641. Use Inspire oxygenator module brackets when Inspire HVR is integral part of Inspire Integrated devices.

CAUTION

- **Brackets shall be cleaned after each use. Only hand cleaning with a soft cloth is allowed. Do not clean with washing machines and do not dip the bracket into washing solutions.**
- **To achieve adequate cleaning and avoid damage or alterations of the bracket, use water, mild soap and other detergents commonly available in the operating room and used for surface cleaning.**
- **The bracket is maintenance free**
- Temperature probes code 042229000 or equivalent temperature probes YSI Series 400 compatible.
- Inspire VAVD kit for venous drainage with vacuum, code 050660. In the USA contact Sorin Group USA Inc. for specific VAVD kits.
- Chest drainage conversion Kit Inspire CDCK for postoperative chest drainage conversion code 050661.
- Currently SORIN GROUP is not aware of any contraindications to the use of the device with occlusive or non-occlusive peristaltic pumps or with centrifugal pumps. The use of other types of pump must be agreed with SORIN GROUP.

R. RETURN OF USED PRODUCTS

Should the user be dissatisfied with anything related to the quality of the product, the product distributor or the authorized local SORIN GROUP representative should be notified.
All the parameters considered critical by the user must be reported with particular care and urgency. The following is the minimum information that should be provided:

- Detailed description of the event and, if pertinent, the conditions of the patient;
- Identification of the product involved;
- Lot number of the product involved;
- Availability of the product involved;
- All the indications the user considers useful in order to understand the origin of the elements of dissatisfaction.

SORIN GROUP reserves the right to authorize, if necessary, recall of the product involved in the notification for assessment. If the product to be returned is contaminated, it must be treated, packed and handled in conformity with the provisions of the legislation in force in the country where the product was used.

CAUTION

It is the responsibility of the health care institution to adequately prepare and identify the product for return shipment. Do not return products that have been exposed to blood borne infectious diseases.

ONLY for US customers

If for any reason the product must be returned to the manufacturer, a returned goods authorisation (RGA) number is required from SORIN GROUP USA Inc. prior to shipping.
If the product has been in contact with blood or blood fluids, it must be thoroughly cleaned and disinfected before packing. It should be shipped in either the original carton or an equivalent carton to prevent damage during shipment, and it should be properly labelled with an RGA number and an indication of the biohazardous nature of the content in the shipment.

CAUTION

It is the responsibility of the health care institution to adequately prepare and identify the product for return shipment. Do not return products that have been exposed to blood borne infectious diseases.

The shipping address for returned goods in the US is:

Sorin Group USA, Inc.
Returned CV Products
14401 West 65th Way
Arvada, CO 80004-3599
FAX (800) 323 4031.

S. LIMITED WARRANTY

This Limited Warranty is in addition to any statutory rights of the Purchaser pursuant to applicable law.

SORIN GROUP warrants that all reasonable care has been taken in the manufacture of this medical device, as required by the nature of the device and the use for which the device is intended.

SORIN GROUP warrants that the medical device is capable of functioning as indicated in the current instructions for use when used in accordance with them by a qualified user and before any expiry date indicated on the packaging.

However, SORIN GROUP cannot guarantee that the user will use the device correctly, nor that incorrect diagnosis or therapy and/or that the particular physical and biological characteristics of an individual patient, do not affect the performance and effectiveness of the device with damaging consequences for the patient, even though the specified instructions for use have been respected.

SORIN GROUP, whilst emphasizing the need to adhere strictly to the instructions for use and to adopt all the precautions necessary for the correct use of the device, cannot assume any responsibility for any loss, damage, expense, incidents or consequences arising directly or indirectly from the improper use of this device.

SORIN GROUP undertakes to replace the medical device in the event that it is defective at the time of placing on the market or whilst being shipped by SORIN GROUP up to the time of delivery to the final user unless such defect has been caused by mishandling by the purchaser.

The above replaces all other warranties explicit or implicit, written or verbal, including warranties of merchantability and fitness for purpose. No person, including any representative, agent, dealer, distributor or intermediary of SORIN GROUP or any other industrial or commercial organization is authorized to make any representation or warranty concerning this medical device except as expressly stated herein. SORIN GROUP disclaims any warranty of merchantability and any warranty of fitness for purpose with regard to this product other than what is expressly stated herein. The purchaser undertakes to comply with the terms of this Limited Warranty and in particular agrees, in the event of a dispute or litigation with SORIN GROUP, not to make claims based on alleged or proven changes or alterations made to this Limited Warranty by any representative, agent, dealer, distributor or other intermediary.

The existing relations between the parties to the contract (also in the case that it is not drawn up in writing) to whom this Warranty is given as well as every dispute related to it or in any way connected to it as well as anything related to it or any dispute concerning this Warranty, its interpretation and execution, nothing excluded and/or reserved, are regulated exclusively by the Italian law and jurisdiction. The court chosen is the Court of Modena (Italy).

K. REINITIATING BYPASS

1) Make sure that the circuit is debubbled.
2) Slowly reopen the venous and arterial lines and start the main pump.
3) Perform perfusion using a suitable technique. Refer to the paragraphs "INITIATING BYPASS" and "DURING BYPASS" in this user's manual.
4) In case of problems or for further clarifications, contact SORIN GROUP or one of its authorized representatives.

L. TERMINATING BYPASS

1) Gradually clamp the venous line and simultaneously decrease blood flow until the main pump stops completely.
2) Clamp the arterial line.

M. BLOOD RECOVERY AFTER BYPASS

1) Recover all the blood contained in the venous line, draining it into the Inspire HVR venous reservoir once the surgeon has removed the venous cannulae.
2) Perfuse as much blood as possible through the aortic cannula.
3) Recover the residual blood in a "transfer" bag. Collected blood can immediately be reinfused or processed with autotransfusion equipment.

N. USE OF VENOUS DRAINAGE WITH VACUUM

This method may be applied at any time during extracorporeal circulation, provided that the instructions below are followed. Using the SORIN GROUP VAVD connection kits or equivalent separately supplied, and a suitable vacuum regulation device allows Inspire HVR to be used with active venous drainage technique with vacuum. This technique constitutes an alternative or a complement to venous drainage by gravity.

1) Open the kit for venous drainage with vacuum, operating in such a way that sterility of the system is not compromised.
2) Connect tubing end for reservoir connection to the vent connector of the venous reservoir (Ref. 8 in Fig.1) and the tubing end for vacuum connection to the vacuum regulating device. The latter must be connected to the vacuum line.
3) Make sure that all Inspire HVR ports are closed.
4) Close the clamp on the branch of the line connected to the reservoir.
5) If necessary to interrupt or suspend this method, open the clamp on the line branch.

WARNING

- It is advisable not to exceed –50 mmHg (-6.66kPa/-0.07bar/-0.97 Psi) negative pressure applied to the reservoir.
- Periodically check functioning of the vacuum regulating device and the level of vacuum inside the Inspire HVR.
- In case a non occlusive pump is used make sure that positive pressure is always applied to the oxygenator module used in conjuction with the device.
- In case the auxiliary/emergency port is required to be used, temporarily suspend vacuum and allow atmospheric pressure into the Inspire HVR before removing its cap and connecting the external cardiotomy reservoir to the auxiliary/emergency port. Also refer to relevant indications and warnings of section I. DURING BYPASS of this instruction for use manual.

O. USE FOR POSTOPERATIVE CHEST DRAINAGE

The use of SORIN GROUP Chest Drainage Conversion Kits/Sets, allow Inspire HVR to be converted into a device for chest drainage and follow the patients in the intensive care unit. The function performed by the resulting device is collecting and filtering chest drainage blood after surgical intervention.

CONTRAINDICATIONS

- When protamine has been administered during surgery before the venous reservoir has been removed from the extracorporeal circuit.
- When there is the certainty or suspicion of gross perforations to the chest wall or an air leak in the lungs.
- Open chest and vacuum applied.
- Use of vented chest tubes that do not have vent flow regulation such as stopcocks.
- If the patient undergoes another operation.

WARNING

- Before use ensure that the Inspire HVR venous reservoir has not been contaminated as a result of uncorrect handling which has compromised sterility.
- The Inspire HVR venous reservoir can function as chest drainage activated by the wall vacuum.
- The sterility of the system depends on the degree of asepsis resulting from use of the venous reservoir and the care taken in connecting the kit during the conversion to chest drainage.
- Prepare the vacuum regulating device with integrated valve following the instructions for use of the manufacturer provided with the device.
- Use a vacuum regulating device fitted with a suitable safety valve that prevents accumulation of positive pressure inside the reservoir.
- Periodically check functioning of the vacuum regulating device.
- If the recovered blood exceeds the amount established by postoperative routine, immediately notify the physician in charge.
- If the recovered blood is to be re-infused, an increase in vacuum will be noted in the reservoir. A filtered venting system must therefore be arranged in order to restore the original negative operating pressure.
- The clinician in charge is solely responsible of the quality of transfused blood and of the technique used to re-transfuse recovered blood.

CONVERSION OF THE INSPIRE HVR INTO A CHEST DRAINAGE DEVICE

Immediately after intraoperative use of the Inspire HVR reservoir, convert it into a chest drainage device using the appropriate chest drainage conversion Kits/Sets and operate in such a way not to compromise sterility of the system. In order to obtain the best out of the chest drainage system, set up the operational routine in such a way that the priming fluid of the extracorporeal circuit generously wets the filter of the Inspire HVR reservoir to the maximum possible level; do not for any reason transfer to the reservoir blood that has not been suitably anticoagulated.

1) Seal all the ports of the Inspire HVR.
2) Set-up the device for connection to the patient and to a suitable vacuum regulator fitted with a safety valve.
3) Position the Inspire HVR venous reservoir suitably close to the patient and in any case at a level lower than the patient: for this purpose use the Inspire BKTH bracket securing it to the bed frame.
4) Make the appropriate connections to the patient chest tubes.
5) Connect Inspire HVR to the vacuum, taking care to place a vacuum regulator with a safety valve between the vacuum source and the Inspire HVR reservoir. The vacuum regulator with safety valve must be extremely reliable and accurate.
6) Adjust the desired degree of negative pressure.
7) Ensure that the safety valve functions properly as per instructions for use of the safety valve in use.
8) Start the drainage procedure and periodically check that the system works regularly.

WARNING

- Use by untrained and unqualified personnel is not permitted.
- All the connections to the Inspire HVR reservoir should be carried out with the utmost care and rapidity in order to prevent contamination.
- The connections and the caps should be checked to assure that the system is tight.
- Always keep the device in a vertical position: do not incline it, not even when the patient is being moved.
- The Inspire HVR reservoir must always be placed at a subthoracic level so that its drainage functions can properly be performed.
- Activate the line vacuum following the instructions provided by the manufacturer of the vacuum regulator.
- It is advisable not to exceed –50 mmHg (-6.66kPa/-0.07bar/-0.97Psi) negative pressure applied to the reservoir.
- Periodically check functioning of the vacuum regulating device and the degree of vacuum.
- Periodically check that the device never works in positive pressure conditions as that could stop drainage and impair patient respiratory function.
- Any re-infusion of recovered blood is on the responsibility and at the discretion of the attending physician.
- The recovered blood may become contaminated and hence not be suitable for retransfusion.
- Filter occlusion during high volume chest drainage may cause blood/fluid overflow cardiotomy filter section.

P. DEVICE CHANGE-OUT

A spare device must always be available during bypass in the unlikely event that the Inspire HVR in use requires change-out. Procedures lasting longer than 6 hours or particular situations where the safety of the patient may be compromised (insufficient performance, leaks, etc.), could require change-out. Follow the steps below to change-out the Inspire HVR reservoir.

WARNING

Use sterile technique during the entire replacement procedures.

1) While the patient is still on bypass, remove the new Inspire HVR reservoir from its outer packaging and from the sterile wrapper; inspect it for damage.
2) Stop suction and clamp the suction lines and connect them to the new Inspire HVR reservoir.

3) Turn the main pump off and double clamp the venous line (5 cm apart) next to the venous inlet port. Clamp the arterial line.
4) Double clamp the pump line next to the reservoir (5 cm apart).
5) Disconnect all monitoring and sampling lines and the temperature probe.
6) Cut the pump line and the venous line in the section between the two clamps, leaving a sufficient length of tubing to allow connection to the new reservoir.
7) Remove the Inspire HVR from the bracket if sterile stand alone.
8) Place a new reservoir onto the bracket. Connect all lines (i.e. pump line to the reservoir outlet port, venous line to the reservoir inlet connector, ...) and temperature probe.
9) Add enough priming solution to the new Inspire HVR to allow extracorporeal circulation being resumed.

WARNING

In this phase, keep the venous and arterial lines clamped.

10) Remove clamp from pump line, from the venous and the arterial line and start the bypass again.
11) Regulate main blood flow and restore suction flow. Adjust gas flow rate as required.
12) Add more priming solution to the new Inspire HVR reservoir as required.
13) Verify all connections and secure with tie straps.
14) The blood contained in the replaced reservoir can be recovered by connecting its outlet line to one of the venous reservoir inlets and draining by gravity.

WARNING

Upon completion of this operation contact SORIN GROUP or an authorised representative to analyse the Inspire HVR considered defective.

Q. MEDICAL DEVICES FOR USE WITH INSPIRE HVR

CAUTION

The user should observe the warnings and cautions and follow instructions for use accompanying the device.

- The Inspire HVR may be used in combination with Inspire 6 M code 050700, Inspire 8 M code 050701, Inspire 6F M code 050702 and Inspire 8F M code 050703 oxygenators.
- A special common interface allows to achieve integrated sterile stand alone devices configuration. Matrix of fig.3 shows full range of available sterile stand alone integrated devices generated by the combination of Inspire HVR and Inspire 6 M, Inspire 8 M, Inspire 6F M and Inspire 8F M.
- The device may be used in combination with an adult or small adult oxygenator module.
- All tubing used to make the circuit connections must be of a diameter which is compatible with the dimensions of the connectors on the device (1/2",3/8",1/4").
- Inspire BKTH bracket code 050641. Use Inspire oxygenator module brackets when Inspire HVR is integral part of Inspire integrated devices.

CAUTION

- **Brackets shall be cleaned after each use. Only hand cleaning with a soft cloth is allowed. Do not clean with washing machines and do not dip the bracket into washing solutions.**
- **To achieve adequate cleaning and avoid damage or alterations of the bracket, use water, mild soap and other detergents commonly available in the operating room and used for surface cleaning.**
- The bracket is maintenance free
- Temperature probes code 042229000 or equivalent temperature probes YSI Series 400 compatible.
- Inspire VAVD kit for venous drainage with vacuum, code 050660. In the USA contact Sorin Group USA Inc. for specific VAVD kits.
- Chest drainage conversion Kit Inspire CDCK for postoperative chest drainage conversion code 050661.
- Currently SORIN GROUP is not aware of any contraindications to the use of the device with occlusive or non-occlusive peristaltic pumps or with centrifugal pumps. The use of other types of pump must be agreed with SORIN GROUP.

R. RETURN OF USED PRODUCTS

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CAUTION

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Returned CV Products
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FAX (800) 323 4031.

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The above replaces all other warranties explicit or implicit, written or verbal, including warranties of merchantability and fitness for purpose. No person, including any representative, agent, dealer, distributor or intermediary of SORIN GROUP or any other industrial or commercial organization is authorized to make any representation or warranty concerning this medical device except as expressly stated herein. SORIN GROUP disclaims any warranty of merchantability and any warranty of fitness for purpose with regard to this product other than what is expressly stated herein. The purchaser undertakes to comply with the terms of this Limited Warranty and in particular agrees, in the event of a dispute or litigation with SORIN GROUP, not to make claims based on alleged or proven changes or alterations made to this Limited Warranty by any representative, agent, dealer, distributor or other intermediary.

The existing relations between the parties to the contract (also in the case that it is not drawn up in writing) to whom this Warranty is given as well as every dispute related to it or in any way connected to it as well as anything related to it or any dispute concerning this Warranty, its interpretation and execution, nothing excluded and/or reserved, are regulated exclusively by the Italian law and jurisdiction. The court chosen is the Court of Modena (Italy).

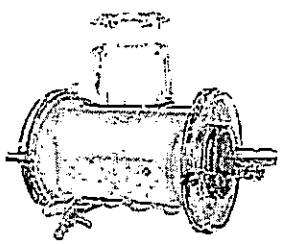
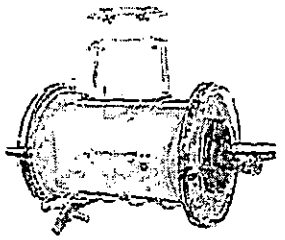
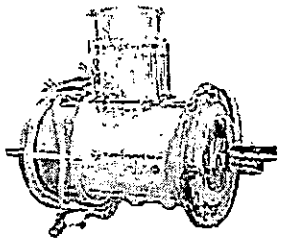
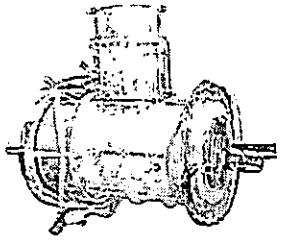
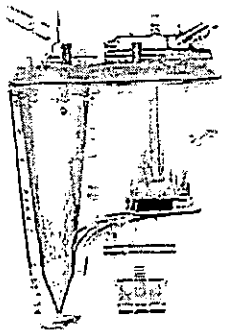
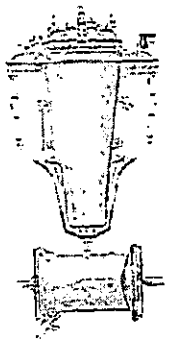
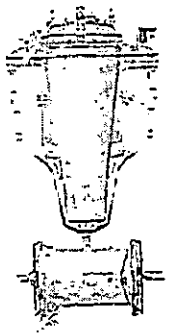
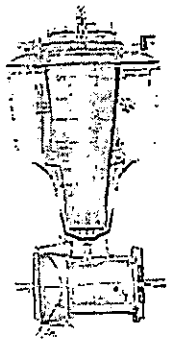
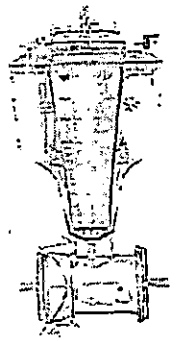
	Sterile Stand Alone Devices for Use with Reference Device	SORIN INSPIRE 6 M  Oxy Module Phisio REF : 050700	SORIN INSPIRE 8 M  Oxy Module Phisio REF : 050701	SORIN INSPIRE 6F M  Oxy Module Phisio with IAF REF : 050702	SORIN INSPIRE 8F M  Oxy Module Phisio with IAF REF : 050703
Sterile Stand Alone Reference Device	Sterile Stand Alone Integrated Devices Generated by Reference Device and Devices for Use with Reference Device	SORIN INSPIRE HVR  Hard Shell Venous Reservoir Phisio REF : 050704	SORIN INSPIRE 6  Integrated Phisio Oxy with HVR Reservoir REF : 050713	SORIN INSPIRE 8  Integrated Phisio Oxy with HVR Reservoir REF : 050714	SORIN INSPIRE 6F  Integrated Phisio Oxy with IAF and HVR Reservoir REF : 050715	SORIN INSPIRE 8F  Integrated Phisio Oxy with IAF and HVR Reservoir REF : 050716

Fig. 3

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 057574 0070 Rev. 00

Manufacturer:

Sorin Group Italia S.r.l.
Via Statale 12 Nord, 86
41037 Mirandola MO
ITALY

Product Category(ies): **Disposable products for cardiopulmonary extracorporeal circulation (ECC), extracorporeal membrane oxygenation (ECMO) and extracorporeal life support (ECLS); disposable products for blood processing, autotransfusion and blood monitoring systems. (as listed in the attachment)**

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.: ITA1292686

Valid from: 2019-06-24
Valid until: 2024-05-26

Date, 2019-06-24

Stefan Preiß
Head of Certification/Notified Body

คณะกรรมการพิจารณาผลการประกวดราคาอิเล็กทรอนิกส์
๑.ลงชื่อ.....ประธานกรรมการ
๒.ลงชื่อ.....กรรมการ
๓.ลงชื่อ.....กรรมการ

Benannt durch/Designated by
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No. G1 057574 0070 Rev. 00

Facility(ies): Sorin Group Italia S.r.l.
Via Statale 12 Nord, 86, 41037 Mirandola MO, ITALY

Attachment:

Product Families	Classification
DIDECO KIDS ARTERIAL FILTERS: Newborn- Infant Arterial filters	IIa
DIDECO MICRO: Newborn- infant, Paediatric and Adult Arterial filters / bubble traps	IIa
VENOUS / CARDIOTOMY RESERVOIRS : Venous Cardiotomy reservoirs	IIa
DIDECO CARDIOPLEGIA SETS: Cardioplegia perfusion sets including also VANGUARD, DIDECO HELIOS and CSC14 Cardioplegia heat exchangers	IIa
CARDIOACCESSORIES/DIDECO CARDIOACCESSORIES: Auxillary devices for cardiac surgery	IIa
HEMOCONCENTRATORS: Infant, paediatric and Adult Haemoconcentrators (DHF & SH models) and sets (KH & D models)	IIa
INSPIRE: adult and small adult oxygenators	IIa
DIDECO D905 EOS Paediatric and small adult oxygenators	IIa
SYNTHESIS: adult oxygenators including also VBT B venous bubble trap	IIa
DIDECO KIDS: new born- infant oxygenators	IIa
DIDECO LILLI PUT 1/LILLI PUT 2: newborn infant oxygenators	IIa
REVOLUTION: centrifugal pumps for extracorporeal circulation	IIa
PERFUSION TUBING SYSTEMS: Perfusion tubing systems for cardiac surgery, ECMO and ECLS, including one or more main components (oxygenator, arterial filter, bubble trap, arterial line, venous line, pump boot tubing, centrifugal pump, hard or soft shell reservoir) feasibly connectable to auxillary lines (secondary, cardioplegia or haemoconcentration sets, connectors or ancillary disposables).	IIa
DIDECO PERFUSION TUBING SYSTEMS: Perfusion tubing systems for cardiac surgery, ECMO and ECLS, including one or more main components (oxygenator, arterial filter, bubble trap, arterial line, venous line, pump boot tubing, centrifugal pump, hard or soft shell reservoir) feasibly connectable to auxillary lines (secondary, cardioplegia or haemoconcentration sets, connectors or ancillary disposables.	IIa
DIDECO COLLECTION SYSTEMS: Autotransfusion collection systems, filters and accessories	IIa
BRAT 2: - Blood bags, collection systems / disposable sets for autotransfusion, PPP, PRP, PLT gel including blood bags	IIb

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๑.ลงชื่อ.....ประธานกรรมการ
๒.ลงชื่อ.....กรรมการ

Benannt durch/Designated by
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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 057574 0070 Rev. 00

- Collection systems / disposable sets without blood bags and accessories for autotransfusion, PPP, PRP, PLT gel	IIa
BOWL: -Blood Bags and wash sets / autotransfusion sets including blood bags - Wash sets / autotransfusion sets without blood bags and accessories for autotransfusion	IIb IIa
ELECTA: - Collection systems / disposable sets for autotransfusion, PPP, PRP, PLT gel including blood bags -Collection systems / disposable sets without blood bags and accessories for autotransfusion, PPP, PRP, PLT gel	IIb IIa
XTRA: -Collection systems / disposable sets for autotransfusion, PPP, PRP, PLT gel including blood bags -Collection systems / disposable sets without blood bags and accessories for autotransfusion, PPP, PRP, PLT gel	IIb IIa
DIDECO DATA MASTER: Blood monitoring disposables connectors	IIa

A4 / 07.17

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๒.ลงชื่อ.....กรรมการ

.....กรรมการ

แบบ บ.น.ท 1

รับรองบางส่วน
หนังสือรับรองประกอบการนำเข้าเครื่องมือแพทย์
สำนักงานคณะกรรมการอาหารและยา
กระทรวงสาธารณสุข

หนังสือเลขที่ ITA 6203643

13 มิถุนายน 2562

ได้พิจารณาหนังสือรับรองการขาย/หนังสือรับรองการขายและหนังสือรับรองระบบคุณภาพการผลิตแล้ว ถูกต้องตามประกาศกระทรวงสาธารณสุข (ฉบับที่ 34) พ.ศ. 2549 แห่งพระราชบัญญัติเครื่องมือแพทย์ พ.ศ. 2531

ชื่อผู้นำเข้า : บริษัท ลีวาโนวา (ไทยแลนด์) จำกัด

ชื่อผู้ผลิต : SORIN GROUP ITALIA S.R.L. (ITALY)

หนังสือฉบับนี้ใช้ประกอบกับ ☑ หนังสือรับรองการขายเลขที่ DGDMF/III/P/I.5.l.e.1/2018/2125

ประเทศ Republic of Italy

☑ หนังสือรับรองระบบคุณภาพการผลิตเลขที่ Q5 18 03 57574 067

สามารถใช้ประกอบการนำเข้าเครื่องมือแพทย์จนถึงวันที่ 17 ธันวาคม 2566

(นางสาวลินินาถ สีสรรค์)
เลขาธิการคณะกรรมการอาหารและยา
ผู้ซึ่งเลขาธิการคณะกรรมการอาหารและยามอบหมาย

เงื่อนไข

1.เมื่อปรากฏว่าประเทศผู้ผลิตหรือประเทศเจ้าของผลิตภัณฑ์ห้ามขาย หรือมีการยกเลิกการรับรองระบบคุณภาพการผลิตของเครื่องมือแพทย์รายการใดตามที่ระบุไว้ในหนังสือรับรองฉบับนี้ ให้ถือว่าการรับรองเครื่องมือแพทย์ดังกล่าวเป็นอันยกเลิก

2. ห้ามนำเลขที่หนังสือไปประกาศโฆษณา

3. ห้ามโฆษณาว่าได้ผ่านการรับรองจากสำนักงานคณะกรรมการอาหารและยา

4. ห้ามโฆษณาเครื่องมือแพทย์ก่อนได้รับความเห็นชอบจากสำนักงานคณะกรรมการอาหารและยา

5. สำนักงานคณะกรรมการอาหารและยา ขอสงวนสิทธิ์ที่จะยกเลิก/เพิกถอนหนังสือรับรองประกอบการนำเข้าเครื่องมือแพทย์ฉบับนี้ หากผู้นำเข้าไม่ดำเนินการให้เป็นไปตามกฎกระทรวงกำหนดหลักเกณฑ์วิธีการ และเงื่อนไข การจดทะเบียนสถานประกอบการนำเข้าเครื่องมือแพทย์ ที่ออกตามพระราชบัญญัติเครื่องมือแพทย์ พ.ศ. 2551 เมื่อกฎกระทรวงดังกล่าวมีผลบังคับใช้แล้ว

หมายเหตุเพิ่มเติม

ข้อมูลที่ผู้ประกอบการบันทึกเข้ามาทั้งหมดถือเป็นความรับผิดชอบของผู้ประกอบการ

คณะกรรมการพิจารณาผลการประกวดราคาอิเล็กทรอนิกส์

๑.ลงชื่อ.....ประธานกรรมการ

๒.ลงชื่อ.....กรรมการ

๓.ลงชื่อ.....กรรมการ

สำนักงานคณะกรรมการอาหารและยา กองควบคุมเครื่องมือแพทย์

รายการนำเข้าผลิตภัณฑ์เครื่องมือแพทย์ ตามหนังสือรับรองเลขที่ ITA 6203643

วันที่อนุมัติ 13/6/2562 วันที่หมดอายุ 17/12/2566

ความหมายของรหัส Owner

1 รหัส 38225 ชื่อเจ้าของ/ผู้ผลิตต่างประเทศ SORIN GROUP ITALIA S.R.L. (ITALY) ประเทศ Italy

ความหมายของรหัส manucd

1 รหัส 38225 ชื่อเจ้าของ/ผู้ผลิตต่างประเทศ SORIN GROUP ITALIA S.R.L. (ITALY) ประเทศ Italy

Owner	manucd	gmpno	catno	offname	pdtname	desc	pageno	umdn	gmdn	RefItemNo
38225	38225	Q5 18 03 57574 067	09085	40 Um Goccia filter	DIDECO COLLECTION SYSTEMS	40 Um Goccia filter	1	11713	35071	6238225000001
38225	38225	Q5 18 03 57574 067	09086	20 Um Goccia filter	DIDECO COLLECTION SYSTEMS	20 Um Goccia filter	1	11713	35071	6238225000002
38225	38225	Q5 18 03 57574 067	09087	20 Um Goccia filter with Infusion line	DIDECO COLLECTION SYSTEMS	20 Um Goccia filter with Infusion line	1	11713	35071	6238225000003
38225	38225	Q5 18 03 57574 067	09088	40 Um Goccia filter with Infusion line	DIDECO COLLECTION SYSTEMS	40 Um Goccia filter with Infusion line	1	11713	35071	6238225000004
38225	38225	Q5 18 03 57574 067	04250	BOWL SET X/55	XTRA	BOWL SET X/55	1	17605	17605	6238225000012
38225	38225	Q5 18 03 57574 067	04251	BOWL SET X/125	XTRA	BOWL SET X/125	1	17605	17605	6238225000013
38225	38225	Q5 18 03 57574 067	04252	BOWL SET X/175	XTRA	BOWL SET X/175	1	17605	17605	6238225000014

สำนักงานคณะกรรมการอาหารและยา กองควบคุมเครื่องมือแพทย์

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วันที่อนุมัติ 13/6/2562 วันที่หมดอายุ 17/12/2566

Owner	manucd	gmpno	catno	offname	pdtname	desc	pageno	umdn	gmdn	RefItemNo
38225	38225	Q5 18 03 57574 067	04253	BOWL SET X/225	XTRA	BOWL SET X/225	2	17605	17605	6238225000015
38225	38225	Q5 18 03 57574 067	04254	PROCEDURE SET TX/55	XTRA	PROCEDURE SET TX/55	2	17605	34863	6238225000016
38225	38225	Q5 18 03 57574 067	04255	PROCEDURE SET TX/ 125	XTRA	PROCEDURE SET TX/125	2	17605	34863	6238225000017
38225	38225	Q5 18 03 57574 067	04256	PROCEDURE SET TX/ 175	XTRA	PROCEDURE SET TX/175	2	17605	34863	6238225000018
38225	38225	Q5 18 03 57574 067	04257	PROCEDURE SET TX/ 225	XTRA	PROCEDURE SET TX/225	2	17605	34863	6238225000019
38225	38225	Q5 18 03 57574 067	04258	XRES T BLOOD COLLECTION RESERVOIR	XTRA	XRES T BLOOD COLLECTION RESERVOIR	2	17605	36966	6238225000020
38225	38225	Q5 18 03 57574 067	04259	XRES B BLOOD COLLECTION RESERVOIR	XTRA	XRES B BLOOD COLLECTION RESERVOIR	2	17605	36966	6238225000021
38225	38225	Q5 18 03 57574 067	04260	COLLECTION SET TX	XTRA	COLLECTION SET TX	2	17605	36966	6238225000023
38225	38225	Q5 18 03 57574 067	04261	PROCEDURE SET BX/55	XTRA	PROCEDURE SET BX/55	2	17605	34863	6238225000024
38225	38225	Q5 18 03 57574 067	04262	PROCEDURE SET BX/ 125	XTRA	PROCEDURE SET BX/125	2	17605	34863	6238225000025
38225	38225	Q5 18 03 57574 067	04264	PROCEDURE SET BX/ 225	XTRA	PROCEDURE SET BX/225	2	17605	34863	6238225000027

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วันที่อนุมัติ 13/6/2562 วันที่หมดอายุ 17/12/2566

Owner	manucd	gmpno	catno	offname	pdtname	desc	pageno	umdn	gmdn	RefItemNo
38225	38225	Q5 18 03 57574 067	04265	COLLECTION SET BX	XTRA	COLLECTION SET BX	2	17605	36966	6238225000028
38225	38225	Q5 18 03 57574 067	04266	COLLECTION SET TX CARDIO	XTRA	COLLECTION SET TX CARDIO	2	17605	36966	6238225000029
38225	38225	Q5 18 03 57574 067	04267	COLLECTION SET BX CARDIO	XTRA	COLLECTION SET BX CARDIO	2	17605	36966	6238225000030
38225	38225	Q5 18 03 57574 067	04015	Sequestration Set X	XTRA	Sequestration Set X	2	16811	17605	6238225000031
38225	38225	Q5 18 03 57574 067	04268	BRB1 BLOOD REINFUSION BAG X 1 Liter	XTRA	BRB1 BLOOD REINFUSION BAG X 1 Liter	2	16752	17605	6238225000032
38225	38225	Q5 18 03 57574 067	04269	Waste Bag X	XTRA	Waste Bag X	2	17605	17605	6238225000033
38225	38225	Q5 18 03 57574 067	04275	XRES B BLOOD COLLECTION RESERVOIR - 120 um	XTRA	XRES B BLOOD COLLECTION RESERVOIR - 120 um	2	17605	36966	6238225000034
38225	38225	Q5 18 03 57574 067	04276	COLLECTION SET BX - 120 um	XTRA	COLLECTION SET BX - 120 um	2	17605	36966	6238225000035
38225	38225	Q5 18 03 57574 067	04277	COLLEC.SET BX CARDIO - 120 um	XTRA	COLLEC.SET BX CARDIO - 120 um	2	17605	36966	6238225000036
38225	38225	Q5 18 03 57574 067	04278	PROCEDURE SET BX/ 225 - 120 um	XTRA	PROCEDURE SET BX/225 - 120 um	2	17605	34863	6238225000037
38225	38225	Q5 18 03 57574 067	05170	3/8" pO2 arterial connector	DIDECO DATA MASTER	3/8" pO2 arterial connector	2	13536	31715	6238225000039

สำนักงานคณะกรรมการอาหารและยา กองควบคุมเครื่องมือแพทย์

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วันที่อนุมัติ 13/6/2562 วันที่หมดอายุ 17/12/2566

Owner	manucd	gmpno	catno	offname	pdtname	desc	pageno	umdn	gmdn	RefItemNo
38225	38225	Q5 18 03 57574 067	05173	1/4" pO2 arterial connector	DIDECO DATA MASTER	1/4" pO2 arterial connector	2	13536	31715	6238225000042
38225	38225	Q5 18 03 57574 067	05340	D731 Micro 27P	DIDECO MICRO	D731 Micro 27P	2	11713	33309	6238225000047
38225	38225	Q5 18 03 57574 067	05341	D733 Micro 40 P	DIDECO MICRO	D733 Micro 40 P	2	11713	33309	6238225000048
38225	38225	Q5 18 03 57574 067	05342	D732 Micro 27A	DIDECO MICRO	D732 Micro 27A	2	11713	33309	6238225000049
38225	38225	Q5 18 03 57574 067	05343	D734 Micro 40A	DIDECO MICRO	D734 Micro 40A	2	11713	33309	6238225000050
38225	38225	Q5 18 03 57574 067	05344	D729 Micro TRAP P	DIDECO MICRO	D729 Micro TRAP P	2	11713	33309	6238225000051
38225	38225	Q5 18 03 57574 067	05345	D730 Micro Trap A	DIDECO MICRO	D730 Micro Trap A	2	11713	33309	6238225000052
38225	38225	Q5 18 03 57574 067	05367	D735 Micro 27 I-New Born	DIDECO MICRO	D735 Micro 27 I-New Born	2	11713	33309	6238225000053
38225	38225	Q5 18 03 57574 067	05368	D736 Micro 40 I-New Born	DIDECO MICRO	D736 Micro 40 I-New Born	2	11713	33309	6238225000054
38225	38225	Q5 18 03 57574 067	05369	D737 Micro Trap I-New Born	DIDECO MICRO	D737 Micro Trap I-New Born	2	11713	33309	6238225000055
38225	38225	Q5 18 03 57574 067	05053	D 540 AUTOTRANSFUSION CONVERSION SET	CARDIOACCESSORIES	D 540 AUTOTRANSFUSION CONVERSION SET	3	14183	42924	6238225000060

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วันที่อนุมัติ 13/6/2562 วันที่หมดอายุ 17/12/2566

Owner	manucd	gmpno	catno	offname	pdtname	desc	pageno	umdn	gmdn	RefItemNo
38225	38225	Q5 18 03 57574 067	05055	D 645 GAS FILTER	CARDIOACCESSORIES	D 645 GAS FILTER	3	15649	42312	6238225000061
38225	38225	Q5 18 03 57574 067	050660	INSPIRE VAVD KIT	CARDIOACCESSORIES	INSPIRE VAVD KIT	4	15012	35441	6238225000120
38225	38225	Q5 18 03 57574 067	050661	INSPIRE CDCK	CARDIOACCESSORIES	INSPIRE CDCK	4	16521	35824	6238225000121
38225	38225	Q5 18 03 57574 067	S351-70	Rigid Fluted tip suction wand with plastic handle 21Fr	CARDIOACCESSORIES	Rigid Fluted tip suction wand with plastic handle 21Fr	4	10749	34923	6238225000128
38225	38225	Q5 18 03 57574 067	S352-80	Rigid Tip with No block System suction wand with plastic handle	CARDIOACCESSORIES	Rigid Tip with No block System suction wand with plastic handle	4	10749	34923	6238225000129
38225	38225	Q5 18 03 57574 067	S900-17	Rigid Fluted tip suction wand with plastic handle 21Fr	CARDIOACCESSORIES	Rigid Fluted tip suction wand with plastic handle 21Fr	4	10749	34923	6238225000133
38225	38225	Q5 18 03 57574 067	050521	EOS ECMO Oxygenating module, PH.I.S.I.O Coated	DIDECO D905 EOS / ECC.O	EOS ECMO Oxygenating module, PH.I.S.I.O Coated	4	17643	17643	6238225000134
38225	38225	Q5 18 03 57574 067	050511	Lilliput 2 ECMO Phisio sterile stand alone	DIDECO D901 LILLIPUT 1 / DIDECO D902 LILLIPUT 2	Lilliput 2 ECMO Phisio sterile stand alone	5	17643	17643	6238225000139
38225	38225	Q5 18 03 57574 067	050713	INSPIRE 6	INSPIRE	INSPIRE 6	5	17643	17643	6238225000142

ลำนักงานคณะกรรมการอาหารและยา กองควบคุมเครื่องมือแพทย์

รายการนำเข้าผลิตภัณฑ์เครื่องมือแพทย์ ตามหนังสือรับรองเลขที่ ITA 6203643

วันที่อนุมัติ 13/6/2562 วันที่หมดอายุ 17/12/2566

Owner	manucd	gmpno	catno	offname	pdtname	desc	pageno	umdn	gmdn	RefItemNo
38225	38225	Q5 18 03 57574 067	050714	INSPIRE 8	INSPIRE	INSPIRE 8	5	17643	17643	6238225000143
38225	38225	Q5 18 03 57574 067	050715	INSPIRE 6F	INSPIRE	INSPIRE 6F	5	17643	17643	6238225000144
38225	38225	Q5 18 03 57574 067	050716	INSPIRE 8F	INSPIRE	INSPIRE 8F	5	17643	17643	6238225000145
38225	38225	Q5 18 03 57574 067	050717	INSPIRE 6 DUAL	INSPIRE	INSPIRE 6 DUAL	5	17643	17643	6238225000146
38225	38225	Q5 18 03 57574 067	050718	INSPIRE 8 DUAL	INSPIRE	INSPIRE 8 DUAL	5	17643	17643	6238225000147
38225	38225	Q5 18 03 57574 067	050719	INSPIRE 6F DUAL	INSPIRE	INSPIRE 6F DUAL	5	17643	17643	6238225000148
38225	38225	Q5 18 03 57574 067	050720	INSPIRE 8F DUAL	INSPIRE	INSPIRE 8F DUAL	5	17643	17643	6238225000149
38225	38225	Q5 18 03 57574 067	05015	D 624 HOLDER FOR NEW BORN INFANT ARTERIAL FILTER	SUPPORTI	D 624 HOLDER FOR NEW BORN INFANT ARTERIAL FILTER	5	15981	41893	6238225000153
38225	38225	Q5 18 03 57574 067	05070	D 713 HOLDER FOR ADULT-PAEDIATRIC ARTERIAL FILTER	SUPPORTI	D 713 HOLDER FOR ADULT-PAEDIATRIC ARTERIAL FILTER	5	15981	41893	6238225000154
38225	38225	Q5 18 03 57574 067	09017	HEMOCONCENTRATOR HOLDER	SUPPORTI	HEMOCONCENTRATOR HOLDER	5	15981	41893	6238225000157
38225	38225	Q5 18 03 57574 067	050641	INSPIRE BKTH	SUPPORTI	INSPIRE BKTH	5	15981	41893	6238225000160

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วันที่อนุมัติ 13/6/2562 วันที่หมดอายุ 17/12/2566

Owner	manucd	gmpno	catno	offname	pdtname	desc	pageno	umdn	gmdn	RefItemNo
38225	38225	Q5 18 03 57574 067	050590	INSPIRE VBT 8 HOLDER	SUPPORTI	INSPIRE VBT 8 HOLDER	5	15981	41893	6238225000163
38225	38225	Q5 18 03 57574 067	A212-45B	Aortic Arch Curved tip with suture flange, wire-reinforced tubing 14Fr/4.5 mm Connector with luer vent	SINGLE-USE CANNULAE FOR EXTRACORPOREAL CIRCUITS	Aortic Arch Curved tip with suture flange, wire-reinforced tubing 14Fr/4.5 mm Connector with luer vent	6	10564	34893	6238225000168
38225	38225	Q5 18 03 57574 067	A212-45C	Aortic Arch Curved tip with suture flange, wire-reinforced tubing 14Fr/4.5 mm Connector without luer vent	SINGLE-USE CANNULAE FOR EXTRACORPOREAL CIRCUITS	Aortic Arch Curved tip with suture flange, wire-reinforced tubing 14Fr/4.5 mm Connector without luer vent	6	10564	34893	6238225000169
38225	38225	Q5 18 03 57574 067	A212-52B	Arterial Cannulae Curved Tip with Suture Flange, Wire-reinforced Tubing- Connector with luer vent down	SINGLE-USE CANNULAE FOR EXTRACORPOREAL CIRCUITS	Arterial Cannulae Curved Tip with Suture Flange, Wire-reinforced Tubing- Connector with luer vent down	6	10564	34893	6238225000170

สำนักงานคณะกรรมการอาหารและยา กองควบคุมเครื่องมือแพทย์

รายการนำเข้าผลิตภัณฑ์เครื่องมือแพทย์ ตามหนังสือรับรองเลขที่ ITA 6203643

วันที่อนุมัติ 13/6/2562 วันที่หมดอายุ 17/12/2566

Owner	manucd	gmpno	catno	offname	pdtname	desc	pageno	umdn	gmdn	RefItemNo
38225	38225	Q5 18 03 57574 067	A212-52C	Arterial Cannulae Curved Tip with Suture Flange, Wire-reinforced Tubing- Connector without luer vent	SINGLE-USE CANNULAE FOR EXTRACORPOREAL CIRCUITS	Arterial Cannulae Curved Tip with Suture Flange, Wire-reinforced Tubing- Connector without luer vent	6	10564	34893	6238225000171
38225	38225	Q5 18 03 57574 067	A212-65B	Arterial Cannulae Curved Tip with Suture Flange, Wire-reinforced Tubing- Connector with luer vent down	SINGLE-USE CANNULAE FOR EXTRACORPOREAL CIRCUITS	Arterial Cannulae Curved Tip with Suture Flange, Wire-reinforced Tubing- Connector with luer vent down	6	10564	34893	6238225000173
38225	38225	Q5 18 03 57574 067	A212-65C	Arterial Cannulae Curved Tip with Suture Flange, Wire-reinforced Tubing- Connector without luer vent	SINGLE-USE CANNULAE FOR EXTRACORPOREAL CIRCUITS	Arterial Cannulae Curved Tip with Suture Flange, Wire-reinforced Tubing- Connector without luer vent	6	10564	34893	6238225000174
38225	38225	Q5 18 03 57574 067	A212-73B	Arterial Cannulae Curved Tip with Suture Flange, Wire-reinforced Tubing- Connector with luer vent down	SINGLE-USE CANNULAE FOR EXTRACORPOREAL CIRCUITS	Arterial Cannulae Curved Tip with Suture Flange, Wire-reinforced Tubing- Connector with luer vent down	6	10564	34893	6238225000176

รายการนำเข้าผลิตภัณฑ์เครื่องมือแพทย์ ตามหนังสือรับรองเลขที่ ITA 6203643

วันที่อนุมัติ 13/6/2562 วันที่หมดอายุ 17/12/2566

Owner	manucd	gmpno	catno	offname	pdtname	desc	pageno	umdn	gmdn	RefItemNo
38225	38225	Q5 18 03 57574 067	A212-73C	Arterial Cannulae Curved Tip with Suture Flange, Wire-reinforced Tubing- Connector without luer vent	SINGLE-USE CANNULAE FOR EXTRACORPOREAL CIRCUITS	Arterial Cannulae Curved Tip with Suture Flange, Wire-reinforced Tubing- Connector without luer vent	6	10564	34893	6238225000177
38225	38225	Q5 18 03 57574 067	A212-80B	Arterial Cannulae Curved Tip with Suture Flange, Wire-reinforced Tubing- Connector with luer vent down	SINGLE-USE CANNULAE FOR EXTRACORPOREAL CIRCUITS	Arterial Cannulae Curved Tip with Suture Flange, Wire-reinforced Tubing- Connector with luer vent down	6	10564	34893	6238225000179
38225	38225	Q5 18 03 57574 067	A212-80C	Arterial Cannulae Curved Tip with Suture Flange, Wire-reinforced Tubing- Connector without luer vent	SINGLE-USE CANNULAE FOR EXTRACORPOREAL CIRCUITS	Arterial Cannulae Curved Tip with Suture Flange, Wire-reinforced Tubing- Connector without luer vent	6	10564	34893	6238225000180
38225	38225	Q5 18 03 57574 067	A222-52B	Arterial Cannulae curved tip with suture collar,wire-reinforced tubing- Connector with luer vent down	SINGLE-USE CANNULAE FOR EXTRACORPOREAL CIRCUITS	Arterial Cannulae curved tip with suture collar,wire-reinforced tubing- Connector with luer vent down	6	10564	34893	6238225000195

สำนักงานคณะกรรมการอาหารและยา กองควบคุมเครื่องมือแพทย์

รายการนำเข้าผลิตภัณฑ์เครื่องมือแพทย์ ตามหนังสือรับรองเลขที่ ITA 6203643

วันที่อนุมัติ 13/6/2562 วันที่หมดอายุ 17/12/2566

Owner	manucd	gmpno	catno	offname	pdtname	desc	pageno	umdn	gmdn	RefItemNo
38225	38225	Q5 18 03 57574 067	A222-52C	Arterial Cannulae curved tip with suture collar,wire-reinforced tubing- Connector without luer vent	SINGLE-USE CANNULAE FOR EXTRACORPOREAL CIRCUITS	Arterial Cannulae curved tip with suture collar,wire-reinforced tubing- Connector without luer vent	7	10564	34893	6238225000196
38225	38225	Q5 18 03 57574 067	A222-65B	Arterial Cannulae curved tip with suture collar,wire-reinforced tubing- Connector with luer vent down	SINGLE-USE CANNULAE FOR EXTRACORPOREAL CIRCUITS	Arterial Cannulae curved tip with suture collar,wire-reinforced tubing- Connector with luer vent down	7	10564	34893	6238225000197
38225	38225	Q5 18 03 57574 067	A222-65C	Arterial Cannulae curved tip with suture collar,wire-reinforced tubing- Connector without luer vent	SINGLE-USE CANNULAE FOR EXTRACORPOREAL CIRCUITS	Arterial Cannulae curved tip with suture collar,wire-reinforced tubing- Connector without luer vent	7	10564	34893	6238225000198
38225	38225	Q5 18 03 57574 067	A222-80B	Arterial Cannulae curved tip with suture collar,wire-reinforced tubing- Connector with luer vent down	SINGLE-USE CANNULAE FOR EXTRACORPOREAL CIRCUITS	Arterial Cannulae curved tip with suture collar,wire-reinforced tubing- Connector with luer vent down	7	10564	34893	6238225000199