Spray

PARAFFIN OIL BASED LUBRICANT FOR SURGICAL INSTRUMENTS

Digitally signed by Bunic Gheorghe
Date: 2023.06.10 10:51:16 EEST
Reason: MoldSign Signature
Location: Moldova

www.franklab.com

Franklab
notre ex

READY FOR USE
instruments guaranteed

LUBRIX Spray

PARAFFIN OIL BASED LUBRICANT FOR SURGICAL INSTRUMENTS

INSTRUCIONS FOR USE

First use:

- Wear protective gloves/ eye protection
- Put the actuator on top of the valve

Instructions for use:

1- Agitate the aerosol before use
2- Hold the aerosol vertically and pulverize in a targeted way the joints of the instruments with short pressions
3- Manipulate the joints several times to ensure a good spread of the product
4- Dry wipe

PRECAUTIONS OF USE

See (SDS 010328)

FEATURES

- Aspect: **Liquid**
- Color: **Colorless**
- pH: **6.5**
- Conservation after opening: **2 years**

COMPOSITION

- Purified paraffin oil
- Emulsifier
- Propellant: nitrogen

PACKAGING

❶ Box of 4 aerosol of 400ml .....ref. **1032856**

Hazardous product - Follow precautions of use. Always read label and product information before use.

Franklab®
notre expertise l'Ultra-Propreté

3 av. des Frênes 78180 MONTIGNY LE BRETONNEUX ■ France
Tél. : + 33 (0)1 39 44 93 40 ■ Fax : + 33 (0)1 39 44 93 41
contact@franklab.com ■ **www.franklab.com**

Développement Durable
Fbecoline by Franklab
ISO 9001 - ISO 13485

fortune medical

SILICONE TRACHEOSTOMY TUBE

100% Silicone for Enhanced Patient Comfort and Great Biocompatibility

ANESTHETIC SERIES

SILICONE TRACHEOSTOMY TUBE

Fortune® Silicone Tracheostomy Tube Features:

- 100% medical grade silicone for superior
- biocompatibility.
- Curved smooth tube and mounted Obturator for easy insertion.
- Standard 15 mm connector.
- X-ray opaque line.
- All cuff models comes with a sensitive pilot balloon allows confirmation of the cuff status.
- Low pressure cuff model provides minimum pressure against trachea wall.
- Neck strap for fixation.
- 15 mm Disconnect Wedge.
- Sterilized double packaging.

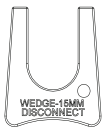
A **Tracheostomy Tube,Cuffless**
B **Tracheostomy Tube, OC Type**
C **Tracheostomy Tube, LC Type**
D **Disconnect Wedge**
E **Neck Strap**

BSI CE 0086

SPECIFICATIONS

Disconnect Wedge:

REF. No.	Size	Description
1500-0000	15 mm	For disconnect 15 mm connector



1500-0000

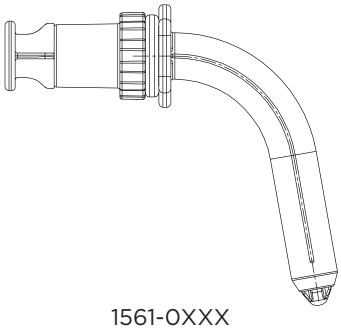
Neck Strap:

REF. No.	Size	Description
1550-0001	Universal	Soft fabric Velcro

1550-0001

Tracheostomy Tube, Cuffless:

REF. No.	Size / I.D.	O.D.	Length	Description
1561-0050	5.0mm	7.3 mm	60 mm	
1561-0060	6.0mm	8.7 mm	65 mm	Cuffless X-ray opaque line Obturator Neck strap Disconnect wedge
1561-0070	7.0mm	10.0 mm	70 mm	
1561-0080	8.0mm	11.3 mm	75 mm	
1561-0090	9.0mm	12.7 mm	80 mm	
1561-0100	10.0mm	14.0 mm	85 mm	



1561-0XXX

ANESTHETIC SERIES

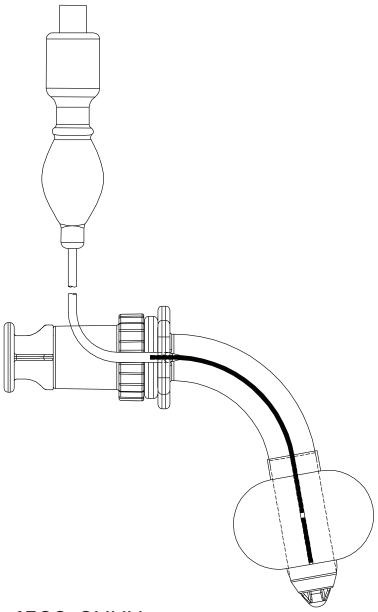
SILICONE TRACHEOSTOMY TUBE

Tracheostomy Tube, OC Type:

REF. No.	Size / I.D.	O.D.	Length	Description
1560-0050	5.0mm	7.3 mm	60 mm	
1560-0060	6.0mm	8.7 mm	65 mm	
1560-0070	7.0mm	10.0 mm	70 mm	Ordinary Cuff X-ray opaque line Obturator Neck strap Disconnect wedge
1560-0080	8.0mm	11.3 mm	75 mm	
1560-0090	9.0mm	12.7 mm	80 mm	
1560-0100	10.0mm	14.0 mm	85 mm	

Tracheostomy Tube, LC Type:

REF. No.	Size / I.D.	O.D.	Length	Description
1565-0050	5.0mm	7.3 mm	60 mm	
1565-0060	6.0mm	8.7 mm	65 mm	
1565-0070	7.0mm	10.0 mm	70 mm	Low Pressure Cuff X-ray opaque line Obturator Neck strap Disconnect wedge
1565-0080	8.0mm	11.3 mm	75 mm	
1565-0090	9.0mm	12.7 mm	80 mm	
1565-0100	10.0mm	14.0 mm	85 mm	



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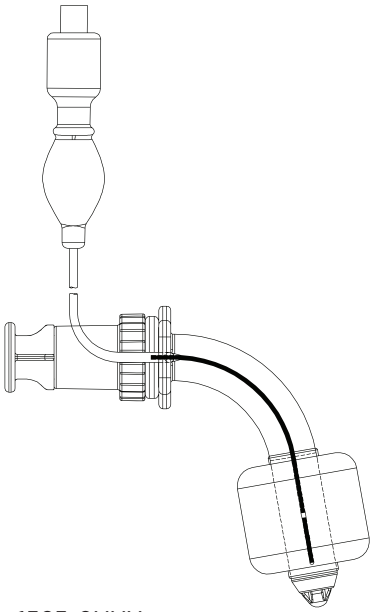

1565-0XXX

fortune medical

6 F., No. 29, Sec. 2, Jhongjheng E. Rd.,
Danshuei Dist, New Taipei City. 251 Taiwan
Tel.:(886) 2-2624-2233 Fax.:(886) 2-2624-2266
www.fortunemed.com Mail:info@fortunemed.com

fortune medical

SILICONE FOLEY BALLOON CATHETER

The Right Choice for Quality Catheters

UROLOGICAL SERIES

EDM UR Eng. V20191115

UROLOGICAL SERIES

SILICONE FOLEY BALLOON CATHETER

Fortune® Silicone 2 way Foley balloon Catheter Features:

- 100% medical grade silicone for superior biocompatibility.
- Transparent medical grade silicone tube allows easy visual inspection and fluid observation.
- X-ray opaque line allows for confirmation of intubated tube using X-ray.
- Soft and uniformly inflated balloon makes the tube sit well against the bladder.
- Smooth round shaft can minimize trauma during insertion and withdrawal.
- 6FR, 8FR and 10FR Pediatric Foley Catheter has disposable stylet for easy insertion.
- Includes an individual sterilized packed Catheter Spigot.
- Sterilized double packaging.
- Firm yet flexible tip designed to aid insertion.
- Recommended usage up to 90 days for 4833 series, of which balloon is more durablel recommended usage up t o29 days for 182X/1856/1830/4822/4856 series.

A **Pediatric**
B **Standard, 5-10 cc/ml**
C **Standard, 20-30 cc/ml**
D **Female**
E **Catheter Spigot**
F **Tiemann Tip**

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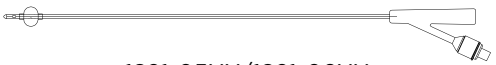
CE 2797

SPECIFICATIONS

2-Way Foley Balloon Catheter, Pediatric:

REF. No.	Size	Balloon	Length	Description
1821-0506	6 FR	1-1.5 cc/ml	330 mm	Stylet X-ray opaque line Catheter spigot
1821-0508	8 FR	2-3 cc/ml		
1821-0510	10 FR	3-5 cc/ml		
1821-0606	6 FR	1-1.5 cc/ml	330 mm	Metal Stylet X-ray opaque line Catheter spigot
1821-0608	8 FR	2-3 cc/ml		
1821-0610	10 FR	3-5 cc/ml		



1821-05XX/1821-06XX

SILICONE FOLEY BALLOON CATHETER

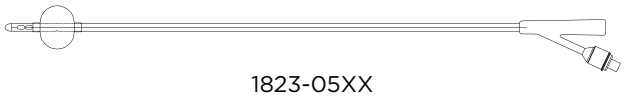
2-Way Foley Balloon Catheter, Standard, 5-10 cc/ml:

REF. No.	Size	Balloon	Length	Description
1822-0512	12 FR	5-10 cc/ml	420 mm	X-ray opaque line Catheter spigot
1822-0514	14 FR			
1822-0516	16 FR			
1822-0518	18 FR			
1822-0520	20 FR			
1822-0522	22 FR			
1822-0524	24 FR			
1822-0526	26 FR			

1822-05XX

2-Way Foley Balloon Catheter, Standard, 20-30 cc/ml:

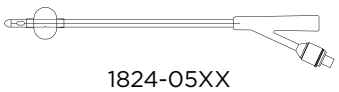
REF. No.	Size	Balloon	Length	Description
1823-0514	14 FR	20-30 cc/ml	420 mm	X-ray opaque line Catheter spigot
1823-0516	16 FR			
1823-0518	18 FR			
1823-0520	20 FR			
1823-0522	22 FR			
1823-0524	24 FR			
1823-0526	26 FR			



1823-05XX

2-Way Foley Balloon Catheter, Female:

REF. No.	Size	Balloon	Length	Description
1824-0512	12 FR	5-10 cc/ml	250 mm	X-ray opaque line Catheter spigot
1824-0514	14 FR			
1824-0516	16 FR			
1824-0518	18 FR			
1824-0520	20 FR			
1824-0522	22 FR			
1824-0524	24 FR			
1824-0526	26 FR			



1824-05XX

2-Way Foley Balloon Catheter, Tiemann Tip:

REF. No.	Size	Balloon	Length	Description
1856-0210	10FR	3-5 cc/ml	420 mm	Tiemann tip X-ray opaque line Catheter spigot
1856-0212	12 FR	5-10 cc/ml		
1856-0214	14 FR			
1856-0216	16 FR			
1856-0218	18 FR			
1856-0220	20 FR			
1856-0222	22 FR			
1856-0224	24 FR			

1856-02XX

Catheter Spigot:

REF. No.	Size	Description
1820-0000	Universal	ABS Sterilized packaging 50 pcs/box

1820-0000

SILICONE FOLEY BALLOON CATHETER

Fortune® Silicone 3-Way Foley Catheter Features:

- 100% medical grade silicone for superior biocompatibility.
- Transparent tube with X-ray opaque line.
- A soft and uniformly inflated balloon makes the tube sit well against the bladder.
- 3-Way design with an attached plug on the irrigation funnel.
- Tapered Central funnel could be connected with irrigation bags.
- Includes an individual sterilized packed Catheter Spigot.
- Sterilized double packaging.
- The tip of 3-way Foley Balloon Catheter with open hole, it could be used together with guide wire for difficulty in catheterization.

A **Silicone 3-Way Foley Balloon**

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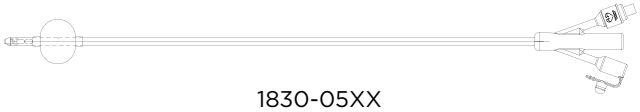
CE 2797

SPECIFICATIONS

3-Way Foley Balloon Catheter

REF. No.	Size	Balloon	Length	Description
1830-0514	14 FR	20-30 cc/ml	420 mm	Attached plug on flushing port X-ray opaque line Catheter spigot
1830-0516	16 FR			
1830-0518	18 FR			
1830-0520	20 FR			
1830-0522	22 FR			
1830-0524	24 FR			
1830-0526	26 FR			



1830-05XX

SILICONE FOLEY BALLOON CATHETER

Fortune® Foley Integrated Balloon Catheter:

Catheter with Integrated Balloon was designed to minimize the discomfort during catheterization procedure. Compare to the ordinary balloon, due to its thickness, creates a conjunction edge after adhered onto the tubing shaft. This conjunction edge between balloon and shaft will eventually increase patient discomfort during insertion and withdrawal.

Fortune® Integrated Balloon Catheter is invented to eliminate the uneven edge out of ordinary balloon. Patented balloon is integrated into the catheter shaft, creates “complete” smooth surface. No conjunction edge between balloon and shaft is formed, which minimizes the friction within the urethra and reduced patient discomfort. Recommended usage up to 90 days for 4833 series, of which balloon is more durablel recommended usage up t o29 days for 4822/4856 series.

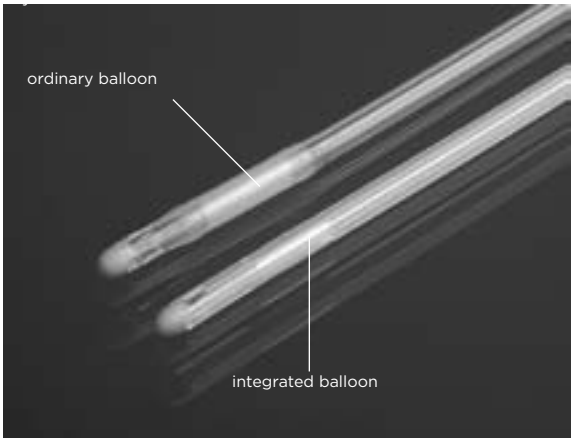
Advantages:

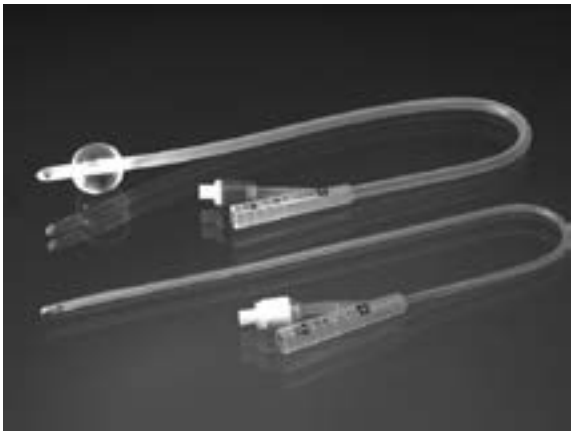
- Patented balloon integrated into the shaft.
- Complete smooth surface.
- Reduce friction within the urethra
- Reduce trauma and secondary harm.
- Reduce discomfort during insertion and withdrawal.
- Reduce accumulation of urine sediment.
- The 4833 series has been successfully passed the long-term balloon test, the balloon filled with 10cc sterile water performed no deflation or rupture after being immersed in the simulate urine for 90 days.

A **Silicone Foley Integrated Balloon Catheter**

B **Silicone Foley Integrated Balloon Catheter, Tiemann Tip**

C **Foley Integrated Balloon Catheter, Long-Term balloon**





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CE 2797

SILICONE FOLEY BALLOON CATHETER

SPECIFICATIONS

Foley Integrated Balloon Catheter:

REF. No.	Size	Balloon	Length	Description
4822-0512	12 FR	5-10 cc/ml	420 mm	Integrated balloon X-ray opaque line Catheter spigot
4822-0514	14 FR			
4822-0516	16 FR			
4822-0518	18 FR			
4822-0520	20 FR			
4822-0522	22 FR			
4822-0524	24 FR			
4822-0526	26 FR			

4822-05XX

Foley Integrated Balloon Catheter, Tiemann Tip:

REF. No.	Size	Balloon	Length	Description
4856-0212	12 FR	5-10 cc/ml	420 mm	Tiemann tip Integrated balloon X-ray opaque line Catheter spigot
4856-0214	14 FR			
4856-0216	16 FR			
4856-0218	18 FR			
4856-0220	20 FR			
4856-0222	22 FR			
4856-0224	24 FR			

4856-02XX

Foley Integrated Balloon Catheter, Long-Term balloon

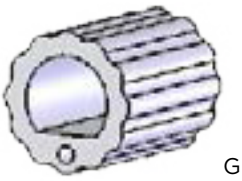
REF. No.	Size	Balloon	Length	Description
4833-0512	12 FR	5-10 cc/ml	420 mm	Integrated , long term balloon X-ray opaque line Catheter spigot
4833-0514	14 FR			
4833-0516	16 FR			
4833-0518	18 FR			
4833-0520	20 FR			
4833-0522	22 FR			
4833-0524	24 FR			
4833-0526	26 FR			

4833-05XX

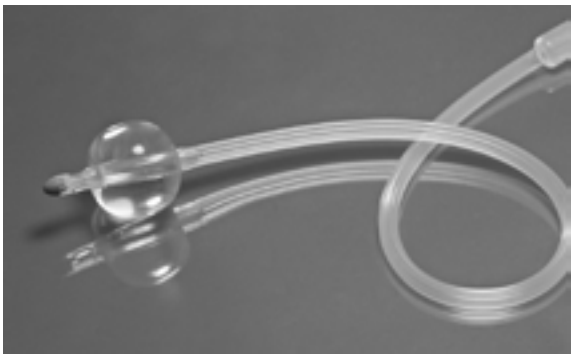
SILICONE FOLEY BALLOON CATHETER ,GROOVED

Fortune® Silicone 2 way Foley balloon grooved Catheter Features:

- 100% medical grade silicone for superior biocompatibility.
- Transparent medical grade silicone tube allows easy visual inspection and fluid observation.
- Grooved catheter was designed to minimize the discomfort during catheterization procedure. With ribs on outer profile of tubes, lubricity of catheter is increased, facilitating easy catheter removal.
- Soft and uniformly inflated balloon makes the tube sit well against the bladder.
- Includes an individual sterilized packed Catheter Spigot.
- Sterilized double packaging.



Grooved Tube



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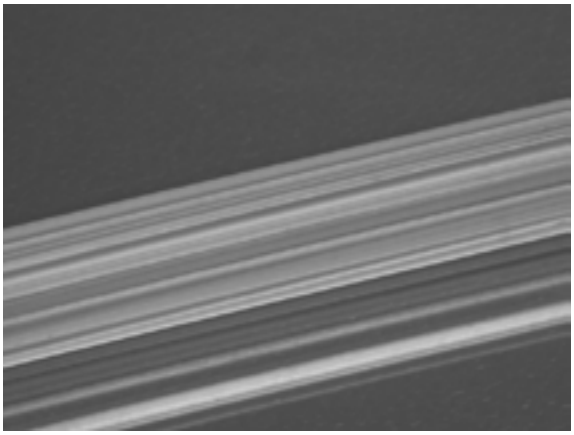

bsi. ISO 13485 Medical Devices Quality Management CE 2797

SPECIFICATIONS

Silicone 2-way Foley balloon catheter, grooved tube

REF. No.	Size	Balloon	Length	Description
1827-0012	12 FR	5-10 cc/ml	420 mm	grooved tube, Catheter spigot
1827-0014	14 FR			
1827-0016	16 FR			
1827-0018	18 FR			
1827-0020	20 FR			
1827-0022	22 FR			
1827-0024	24 FR			

1827-0018

Tube Section

I.P. "AGENȚIA SERVICII PUBLICE"
Departamentul înregistrare și licențiere a unităților de drept

Extras
din Registrul de stat al persoanelor juridice
nr. **104076** din **02.11.2022**

Denumirea completă: **Societatea cu Răspundere Limitată "ERICON"**
Denumirea prescurtată: **"ERICON" S.R.L.**
Forma juridică de organizare: **Societate cu răspundere limitată**
Numărul de identificare de stat și codul fiscal: **1003600000316**
Data înregistrării de stat: **20.10.1992**
Sediu: **MD-2003, strada Vasile Lupu 6, or. Durleşti, mun. Chişinău, Republica Moldova**
Genurile de activitate:

1. **Editarea cărţilor, broşurilor şi altor publicaţii;**
2. **Tipărirea ziarelor;**
3. **Publicitate;**
4. **Comerţul cu amănuntul al cărţilor, ziarelor şi rechizitelor de birou;**
5. **Comerţul cu amănuntul al articolelor medicale şi ortopedice;**

Capitalul social: **449852 Lei**
Administrator(i): **BUNIC GHEORGHE**
Asociați:

1. **BUNIC GHEORGHE, partea socială 449852 Lei, ce constituie 100%**

Beneficiari efectivi: **Nedeclarat**

Prezentul extras este eliberat în temeiul art. 34 al Legii nr.220/2007 privind înregistrarea de stat a persoanelor juridice şi a întreprinzătorilor individuali şi confirmă datele din Registrul de stat la data de 02.11.2022

Specialist coordonator
Aliona Lazari
tel. 022-207840

EB 0422800

REPUBLICA MOLDOVA

CERTIFICAT DE ÎNREGISTRARE

SOCIETATEA CU RĂSPUNDERE LIMITATĂ "ERICON"

ESTE ÎNREGISTRATĂ LA CAMERA ÎNREGISTRĂRII DE STAT

Numărul de indentificare de stat - codul fiscal

1003600000316

Data înregistrării **20.10.1992**

Data eliberării **19.04.2005**

Dragomir Ala, registrator de stat

Funcția, numele, prenumele persoanei care a eliberat certificatul

semnătura

CAMERA ÎNREGISTRĂRII DE STAT 177

MD 0033559

bsi.

By Royal Charter

EC Certificate - Full Quality Assurance System

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

No. **CE 588902**

Issued To: **Fortune Medical Instrument Corp**
6F., No. 29, Sec. 2, Jhongjheng E.Rd.,
Danshuei Dist,
New Taipei City
251
Taiwan

In respect of:

The design, manufacture and final inspection of sterile urological catheters and accessories, drainage tube and accessories, endotracheal tube, tracheostomy tube, reservoir, gastrointestinal tube and accessories, silicone surgical ruler and silicone vessel ID loops and non-sterile laryngeal mask tube.

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

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

S M Brain

Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: 2012-08-27 **Date: 2018-10-05** **Expiry Date: 2023-09-24**

...making excellence a habit.

GMED
GROUPE LNE

ATTESTATION / *CERTIFICATE* / CERTIFICADO n° 28791 rev. 13
Délivrée à Paris le 07 mai 2021
Issued in Paris on May 7th, 2021
Establecido en Paris, el 07 mayo 2021

ATTESTATION CE / *EC CERTIFICATE* / CERTIFICADO CE

Approbation du Système Complet d'assurance Qualité/ *Approval of full Quality Assurance System*
Aprobación del sistema completo de Seguro de la calidad
ANNEXE II excluant le point 4 Directive 93/42/CEE relative aux dispositifs médicaux
ANNEX II excluding section 4 Directive 93/42/EEC concerning medical devices
ANEXO II excluyendo el punto 4 Directiva 93/42/CEE relativa a los productos sanitarios
Pour les dispositifs de classe III, un certificat CE de conception est requis
For class III devices, a EC design certificate is required

Fabricant / ***Manufacturer*** / Fabricante

FRANKLAB
3, avenue des Frênes - ZA de l'Observatoire
78180 MONTIGNY LE BRETONNEUX FRANCE

Catégorie du(des) dispositif(s) / ***Device(s) category*** / Categoría del producto

Détergents-désinfectants et désinfectants pour dispositifs médicaux invasifs.

Detergents-disinfectants and disinfectants for invasive medical devices.

Detergentes-desinfectantes y desinfectantes para dispositivos médicos invasivos.

Voir document complémentaire GMED / See GMED additional document
n° 38469

GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé P177202 - P601161, le système d'assurance qualité - pour la conception, la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe II excluant le point 4 de la Directive 93/42/CEE.

GMED certifies that, on the basis of the results contained in the file referenced P177202 - P601161, the quality system - for design, manufacturing, and final inspection - of medical devices listed here above complies with the requirements of the Directive 93/42/EEC, annex II excluding section 4..

GMED certifica que después del examen de los resultados indicados en el expediente P177202 - P601161, el sistema de calidad para el diseño, la fabricación y el control final - de los productos sanitarios enunciados anteriormente - cumple con los requisitos del anexo II excluyendo el punto 4 de la Directiva 93/42/CEE.

La validité du présent certificat est soumise à une vérification périodique ou imprévue
The validity of the certificate is subject to periodic or unexpected verification

Début de validité / ***Effective date*** / Fecha efectiva : **May 7th, 2021 (included)**

Valable jusqu'au / ***Expiry date*** / Fecha de expiración : **May 26th, 2024 (included)**

Docusigned by:
Beatrice Lys
GMED

On behalf of the President
Béatrice LYS
Technical Director

GMED - 28791 rev. 13
Modifie le certificat 28791-12