GLUBRAN®2

The gentle power of a drop.

—

Class III medical device, synthetic, CE certified for surgical and endovascular use

GEM SOLUTION COMES FROM EVOLUTION.

Summary

SUPPORTING THE SURGEON, WITH BETTER RESULTS FOR PATIENTS.

25 years sustaining surgery.

The evolution of GEM derives from its continuing commitment to research and efforts to improve products and demonstrate their effectiveness and quality, not only through the contribution of our expert professionals, but also through clinical studies on the most innovative devices.

GENERAL SURGERY 37-84

CANCER SURGERY
61,64,66,69,73,74,82,84-86,89,94,97

UROLOGY 95-105

GYNECOLOGY 93,94,100

THORACIC SURGERY 85-92

NEUROSURGERY 20-21

DENTAL SURGERY 22,26,27,191,193,196

OTOLARYNGOLOGY 22-28

VASCULAR SURGERY
143,146, 154,162

PEDIATRIC SURGERY 29-36, 99

CARDIAC SURGERY 12-19

DIGESTIVE ENDOSCOPY 110-136

INTERVENTIONAL RADIOLOGY AND NEURORADIOLOGY
3,6,77,87,110,118,121,125,134, 137-190

—

ADHESIVE

SEALANT

HEMOSTATIC

BACTERIOSTATIC

SCLEROSING

EMBOLIZING

—

A REVOLUTION, IN A DROP.

Glubran 2 for minimally invasive surgery.

- **Versatile, polymerizes quickly in contact with tissue and in a moist environment** [59,98,100,159]
- **Creates a thin, elastic, breathable film, firmly adhering to tissues or prosthetic materials** [2,7,30,65,84,91]

UNIQUE FORMULA commercially available

A second generation product modified by the addition of a monomer

N-Butyl 2 Cyanoacrylate (NBCA)+ Methacryloxysulfolane (MS)

SIX PRODUCTS IN ONE DROP.

SIX properties in ONE SINGLE product, for over 80 surgical indications.

ADHESIVE

High tensile strength: the minimum acceptable load is 435 N [approx. 18 kg/cm2]. [1,2,13,16]

SEALANT

Applied using dedicated nebulizers, it forms a thin film with sealing and waterproofing properties, thanks to its synthetic nature and high adhesive power. [2,27,30,64-68,77,88,91,106-108]

HEMOSTATIC

Reacts with blood, even when uncoagulated, inducing "mechanical" hemostasis at the site of bleeding. [7,62,63,95-97-116-119,121-127,131-134]

BACTERIOSTATIC

Inhibits bacterial proliferation for an average of 7 days. [1,5,7,10,11,28, 34,76,115]

SCLEROSING

Injected into the lumen of the vessel/varix, it polymerizes, generating local thrombosis and resulting fibrosis and sclerosis. [5,113,128-132,135]

LIQUID EMBOLIZING AGENT

Injected into the blood vessel it polymerizes, forming a tight-fitting mold to the walls of the vessel and occluding it. This generates a definitive occlusion, equivalent to a surgical ligature. [3,6,77,87,110,118,121,125,134,137-190]


Pediatric surgery
Plastic Surgery
General surgery
Thoracic surgery
Urological surgery
ENT.
Sealant
Adhesive
Gynecological surgery
Vascular surgery
Bacteriostatic
GLUBRAN 2
Hemostatic
Cardiac surgery
Neurosurgery
Embolizing
Sclerosing
Radiology, Neuroradiology, Cardiology Interventional
Digestive endoscopy

When it makes a difference.

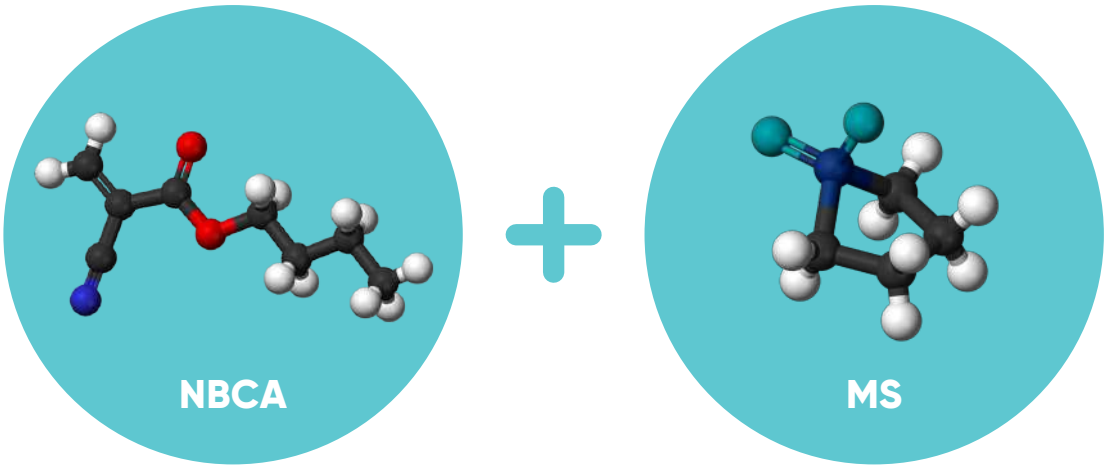
GLUBRAN 2

A GREAT ADHESIVE AND EXCELLENT BACTERIOSTATIC SEALANT.*

- It also interacts and reacts with liquids other than blood: serum, lymph, gastric and pancreatic juices, bile, saliva, urine.
- Reacts with blood, even when uncoagulated, inducing "mechanical" hemostasis at the site of bleeding . [63-84,95,98-109,197]
- Hemostasis is ensured, even in anticoagulated patients or in patients with hereditary coagulopathies. [103,143,146,161]

*1,2,5,7,10, 11,13,27,28,30,34,64-68,77,88,91,106-108,192

RELIABLE BIOCHEMISTRY.



Appearance

TRANSPARENT

Smell

TYPICAL OF CYANOACRYLATES

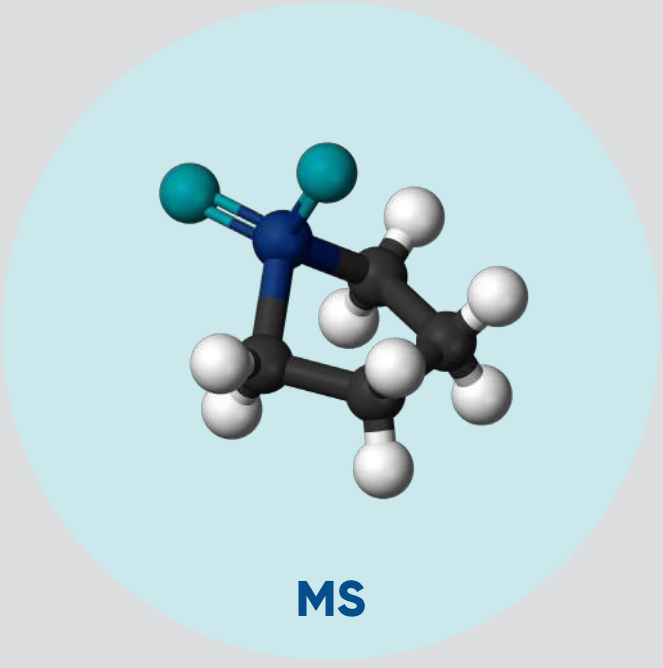
Density

SIMILAR TO WATER [1]

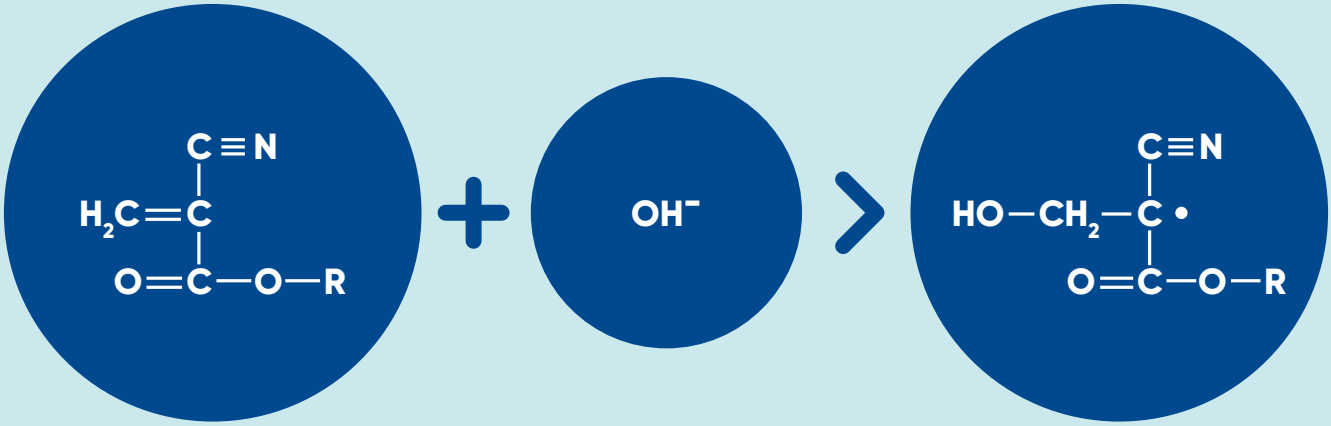
- **Ready to use** [1,7,35,37,196]
- **Does NOT polymerize in the presence of air** [142]
- **Storage between +2 and +8 °C**
- **Can stay at room temperature (22.5+/-2.5 °C) for 48 hours** [1]
- **Effective in moist environment** [1,59,98,100,159]

The advantages of MS:

- Polymerization temperature: 45 °C, much lower than 80-90 °C typical of pure monomeric cyanoacrylates [6,8,59, 98,100,159]
- Biocompatibility [1,2,5,7,200]
- NO tissue necrosis [3,7,6,172]
- Elasticity of the film at the end of polymerization [2,7,30,65,84,91]



POLYMERIZATION [192,194,198]



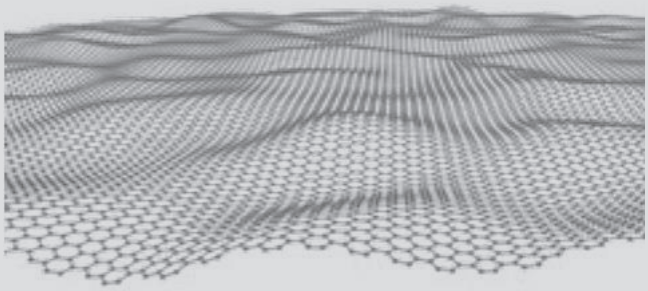
MONOMER

ions trigger polymerization

unstable intermediate monomer

In:

- **Moist environments and tissues**
- **BLOOD or OTHER BODY FLUIDS (serum, lymph, gastric or pancreatic juices, bile, saliva, urine)**
- **Polymerizes after 1-2 seconds, complete after 60-90 sec**



- During polymerization a thin, elastic film is formed that adapts to the anatomy of the tissues. [106-108]
- At the end of polymerization, the surface of the film is no longer adhesive. [8]

NOTE

Distilled water/glucose/mannitol do not activate polymerization [3,7,6,172]


Zero
residue,
zero traces.

A BIODEGRADABLE FILM.

HYDROLYTIC DEGRADATION

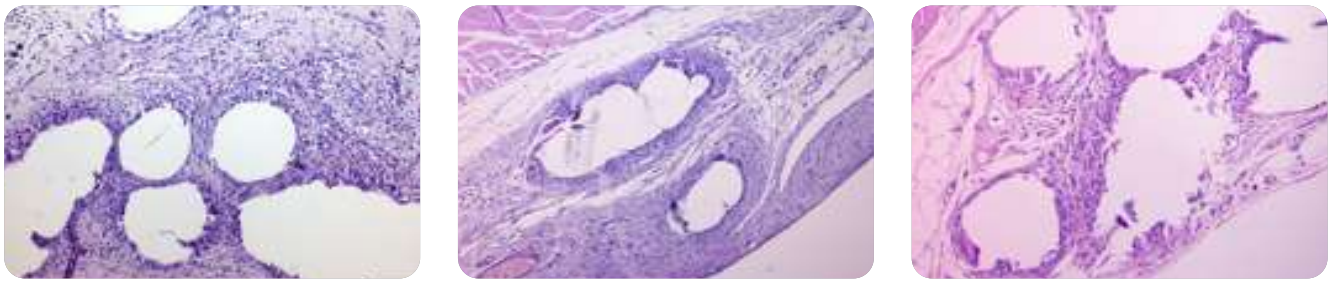
Carboxylesterases circulating in the blood BIODEGRADE Glubran® 2 by means of hydrolytic mechanisms, in a period ranging from 15 days to 6 months.

The degradation products are excreted from the body through the kidneys and pulmonary excretion. [65]

In more vascularized tissues, elimination is faster. [55,200]

Glubran® 2 does not stop the healing and tissue regeneration process.

The same newly formed tissue cells penetrate the film of Glubran® 2 and continue to colonize it and reproduce, until it is eliminated. [55,200]



7 DAYS | **15 DAYS** | **30 DAYS**

Histological samples of abdominal wall cross-sections of rats undergoing hernia repair with prosthesis fixation using Glubran® 2. Interaction between prosthetic mesh fibers and host tissues at 7, 15 and 30 days after surgery (Modified by Poli et Al. 2019). [200]

A DROP OF SAFETY.*

BIOCOMPATIBILITY TEST [1]

- Cytotoxicity
- Genotoxicity
- Mutagenicity

TISSUE TESTS [1]

- Intracutaneous reactivity on rabbit
- Allergic sensitization on guinea pig
- Muscle implantation test in rabbit

RESULTS

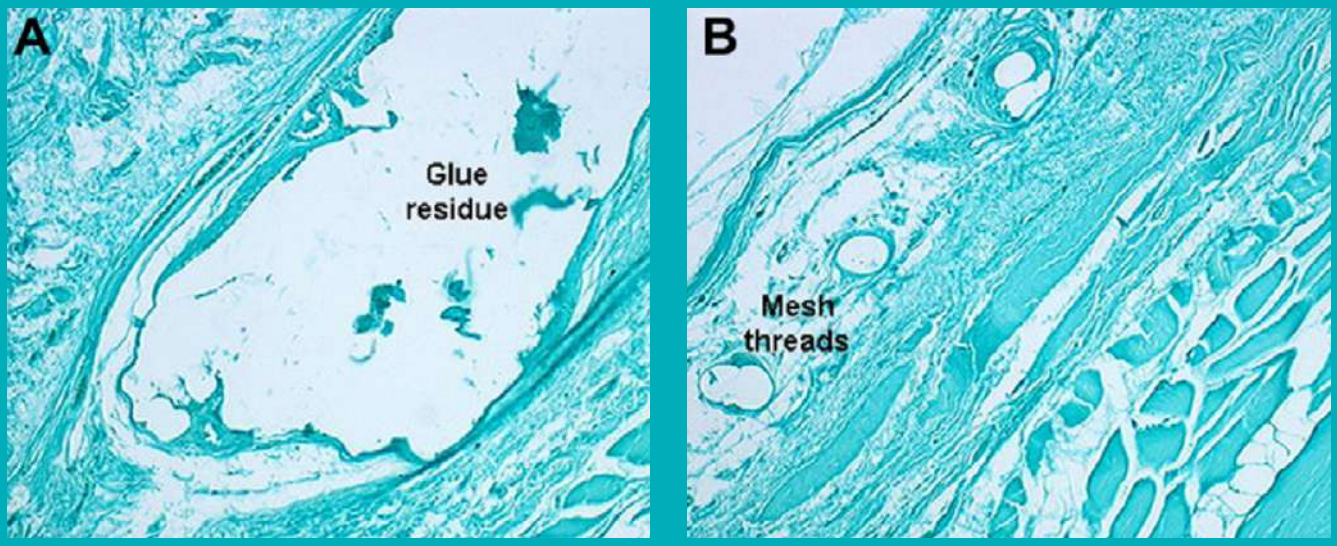
The product causes moderate inflammation, typical of foreign body reactions such as suture threads [1,7,200]

NO chronic inflammation [1,3,6,7,200]

Once polymerization is complete, Glubran® 2 behaves like an INERT BIOMATERIAL [1,2,7,27,78,202]

- Over 2 MLN treatments
- 25 years of safety
- Over 200 publications

*52,161,166,192,194,201



"Cyanoacrylate surgical glue as an alternative to suture stitches in fixing meshes for hernia repair." [7]

- **... No PMN (PolyMorphoNucleated), necrotic cells or apoptotic cells were observed.**
- *"...when cyanoacrylates with longer alkyl chains (longer degradation) were finally synthesized, these began to be used clinically without histotoxicity..."* [192]

Constantly evolving solutions.

1 ml / 0.5 ml / 0.25 ml

10 sterile single-dose aluminum blister packs

Shelf life 2 years

CUSTOM APPLICATIONS.

Wide range of dedicated applicators.

Devices for drop-by-drop applications

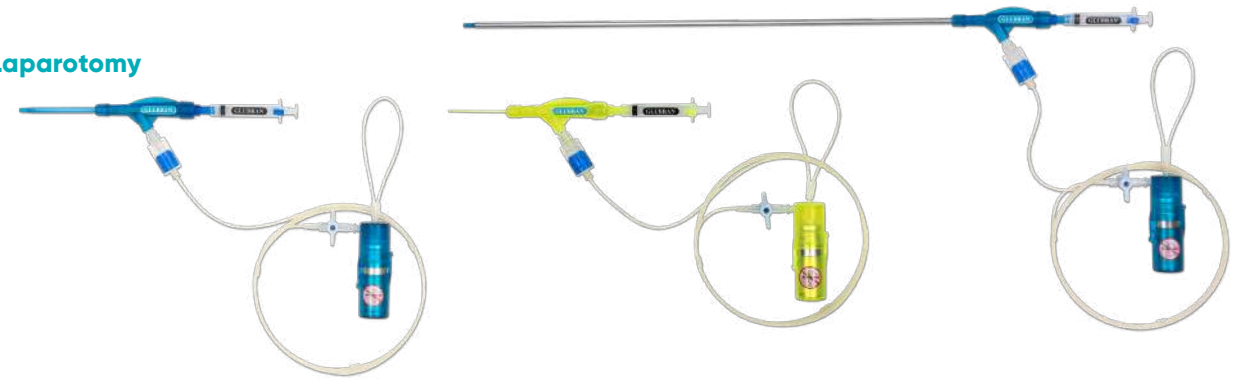
Tip for thin linear application

Laparoscopic catheters for drop-by-drop application

Nebulizers for:

Laparoscopy

Laparotomy



GLUTACK

Laparoscopic atraumatic fixing device for hernia prostheses

AS A BACTERIOSTATIC SEALANT

GENERAL SURGERY

To prevent and reduce

Micro-leakage and extravasation of fluids with consequent formation of fistulae, seromas and lymphorrhoea.

To seal

- Anastomosis (vascular, gastrointestinal, biliary, urological) [2,5,7,29,192,194]
- Sutures [7,9,19,26,28,43,47,66,85]
- Manual and mechanical resection lines [15,63-66,82,106]
- Resection surfaces of parenchyma and organs (liver, kidneys, pancreas, spleen, lungs) [69,70,81,82,85,86,91,95,97,192]
- Surgical cavities following removal of organs or tumor masses [74,84,94,97]

To treat

- Fistulae (biliary, anal, perianal, urinary, pharyngeal, liquoral, bronchial, pleural, esophageal, tracheoesophageal, gastric, gastrointestinal, duodenal and pancreatic) [22,32,75-80,88,90,92,99,110-115]

LIVER SURGERY

To prevent

The formation of bilomas and biliary leaks after liver surgery and cholecystectomy [81,82,152,159]

THORACIC SURGERY

For aerostasis

Pulmonary resection interventions, lobectomies, pneumonectomies, bullectomies, volume reductions, tracheobronchial resections [85-92]

NEUROSURGERY

To seal

- Sutures of cranial and spinal dural plastic surgery in combination with other products (gauze, hemostatic sponges) [20]
- The transsphenoidal access of the Turkish saddle, for removal of pituitary adenomas [21]

BREAST AND GYNECOLOGICAL SURGERY

To close and seal

- Sectioned lymphatic vessels to prevent and reduce the formation of seromas and lymphorrhoea [84,94]

AS A SURGICAL ADHESIVE

SURGERY

To fix

- Hernia prostheses [4,7,9,37-60,93]
- Prostheses in sacrocolpopexy [93]
- In vaginal, perineal, uterine plastic surgery [24-25]
- Omentum [106-108,204]
- Fabric patches (biological and synthetic) [6,12-14,27,61,105]

To replace sutures in

- Repair of small epicardial lacerations [14-16,208]
- Timpanoplasty [24,25]
- Uvuloplasty [28]
- Circumcision, phimosis and frenulotomy [33-35,103]
- Closing trocar insertion points
- Surgical wounds [10,11,26,47,192,207,20]
- Dental surgery [22,26,27,193]

To glue

- Damaged tissue [17,27, 205,206]
- Bone and osseocartilaginous fragments [207]
- Tracheoesophageal phonation valves

To occlude

- Fistulae
- Ducts (billiary, pancreatic, etc.)
- Canals (lymphatic etc.) [22,32,75-80,88,90,92,99,110,115]

AS A HEMOSTATIC

FOR ALL TYPES OF SURGERY

- Blocks punctate bleeding
- Adheres firmly to hemorrhage sites
- Adapts to micro folds of tissues

A simple and effective solution to achieve rapid hemostasis in [7,62,63,95-97-116-119,121-127,131-134]

- Injuries with punctate bleeding after oncological surgery with partial or total removal of an organ
- Resection surfaces of various organs (liver, kidneys, spleen, pancreas, lung)
- Vascular and cardiac surgical anastomoses (arterial and venous bypass, arteriovenous, prosthetic-vascular fistulae, aneurysm repair)
- Bleeding oropharyngeal surfaces
- Parenchyma tissue on lacerations, hemorrhagic lesions
- Cholecystic bed, bladder bed
- Ovarian cysts, myomectomies, hysterectomies
- Gastro-duodenal ulcers, with endoscopic injection into the submucosa

AS A SCLEROSING AGENT

The endoscopists assistant [110-190]

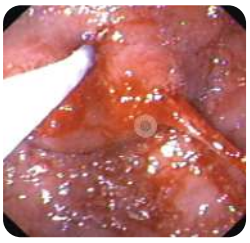
When injected into varices (Esophageal, Gastric, Duodenal) polymerizes and occludes the vessel, inducing sclerosis. [5,113,128-132,135]

BLEEDING VARICES

1. Bleeding of Varices
2. Injection of Glubran® 2
3. **Occluded Varix**

Endoscopic treatment of gastric varices (Author Prof. G. Battaglia)

1.



2.

3.

AS A LIQUID EMBOLIZING AGENT

Interventional radiologists assistant (body and head-neck)

3,6,77,87,110,118,121,125,134, 137-190

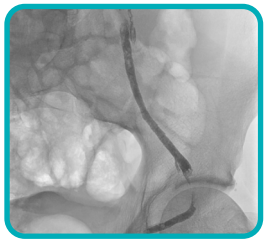
- Injected into the blood vessel, it polymerizes, forming a mold which adheres to the walls of the vessel, obstructing it and causing a definitive occlusion without recanalization.

VARICOCELES [142]

Pre-embolization

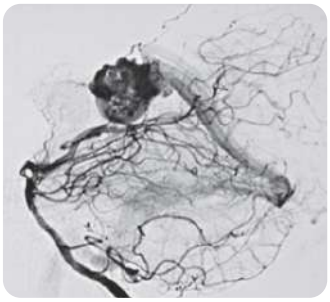
Microcatheterization

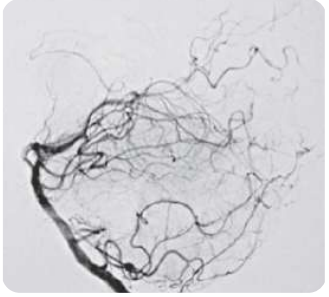
Post-embolization

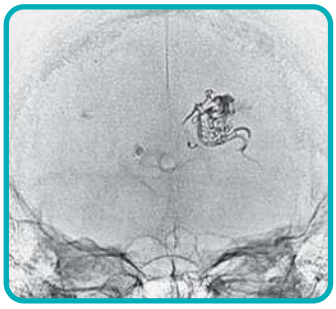


AVM EMBOLIZATION [142,190]

Bleeding of AVM before and after injection of Glubran® 2 with **complete obliteration and resolution.**







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General Surgery

Prostheses Fixation

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CERTIFIED QUALITY.

Thanks to the group efforts of a team of clinical and regulatory certification professionals, GEM's quality system and production process has obtained the following certification

ISO 13485:2016 and ISO 9001:2015. GEM is also MDSAP certified as the devices produced are authorized for sale in Canada, Brazil and Australia.

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Rev. 00 - Ed. 06/07/2020