Anexa nr. 1
La Procedurile administrative pentru notificarea dispozitivelor medicale care deţin marcajul CE

Către Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. 1 din 13.10.2023

Solicitantul SRL Biosistem mld, cu sediul str. Albişoara 16/1 of.7, or. Chişinău
(adresa)
Tel./Fax: .+373-22-808517, +373-22-808719, fax +373-22-808519, e-mail biosistem.mld@gmail.com; info@biosistem-mld.com, solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii şi tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

- Surgical Glue GLUBRAN

Se anexează următoarele acte:
Declaraţie pe proprie răspundere
CE certificate
Declaratie de conformitate
Scrisoare de imputernicire

Digitally signed by Poiata Vitalie
Date: 2023.10.13 17:09:37 EEST
Reason: MoldSign Signature
Location: Moldova

Data 13.10.2023 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	

Digitally signed by Kojevnikov Dmitrii
Date: 2023.10.13 17:11:25 EEST
Reason: MoldSign Signature
Location: Moldova

Anexa nr. 2
La Procedurile administrative pentru notificarea
dispozitivelor medicale care dețin marcajul CE

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAŢIE PE PROPRIE RĂSPUNDERE

Solicitant: SRL Biosistem mld, cu sediul str. Albișoara 16/1 of.7, or. Chișinău, declar pe proprie răspundere, cunoscând prevederile art. **352[1]**, Codul Penal al Republicii Moldova cu privire la falsul în declaraţii, că documentele și datele furnizate pentru notificarea dispozitivului medical:

- Surgical Glue GLUBRAN

Sunt autentice și corespund realității.

Administrator: Poiata Vitalie *Semnătura* _____

Data 13.10.2023

Strada Vulturilor nr. 56-58, Etaj 2, Apt. 23, Sector 3, Bucuresti 030856
telefon +40 374 010571 ◆ fax +40 374 091317
office@insight-trading.ro ◆ www.insight-trading.ro
Nr. Registrul comertului J40/1538/2011 ◆ Cod identificare fiscala RO28030982
Capital social: 51.000 Lei
ING Bank Sucursala Bucuresti ◆ IBAN Lei RO62 INGB 0000 9999 0235 3209
Trezoreria Sector 3 ◆ IBAN RO22 TREZ 7035 069X XX02 1117

Management System certification ISO 9001 ISO 13485

To: Whomever it may concern

Biosistem-mld SRL
Albisoara 16/1 ap.7
Chisinau, R. Moldova

Bucharest, 06.10.2023

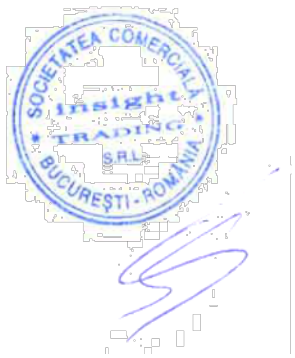
AUTHORIZATION

We, Insight Trading S.R.L. with principal place of business at Bucharest, 56-58 Vulturilor street, as authorised distributor for GEM Srl, manufacturer of medical products with principal place of business at Via dei Campi 2- 55049 Viareggio (LU) Italy, hereby confirm that **Biosistem mld SRL** with business office at Albisoara 16/1 ap.7, Chisinau, Republic of Moldova, is authorized to carry out the registration of products manufactured by GEM Srl.

This authorization is valid for 1 year from the date of issuance and the manufacturer issues automatically renewable if no termination letter.

Bogdan Scripca

Administrator



MERITMEDICAL GORE Creative Technologies Worldwide GEM GLUBRAN2

SALES SPECIFICATIONS AGREEMENT

Manufacturer name and address:	**GEM Srl** – Via dei Campi 2 – 55049 Viareggio (LU) ITALY Tel. +39 0584 391388/389784 Fax. +39 0584 397904 Web site: www.gemitaly.it E-mail address: info@gemitaly.it
Distributor's name and address:	**Insight Trading SRL** - Strada Vulturilor nr. 56-58, Et. 2, Apt. 23, București 030856, România Tel. +40 374 010571 Fax: +40 374 091317 E-mail address: office@insight-trading.ro

Stamp and signature of *DISTRIBUTOR* for acceptance:

Rev.	Date	Changes	Prepared by: AQ	Checked by: DC	Approved by: DT
00	23/06/2020	General revision align with the requirements of the regulation (EU) 2017/745			
01	02/03/2022	Revison of the point 3 – Art.14 MDR 2017/745	I. Tarabella	I. Vitturini	L. Branchetti

Legend: CSQ = Quality Management System, Regulatory Affairs and CE Mark external Consultant, AQ = Quality Assurance Responsible and Management Representative, DC = Sales Management, SGQ = Quality Management System, MQ = Quality Manual, MS = Job Description, PG = Management Procedure, PT = Technical Procedure, IO = Standard Operating Procedure, PC = Control Plan, CA = Quality Agreement Specifications, FT = Technical File, Mod. = Form, DdT = Transport Document, DMR = Device Master Record, DHR = Device History Record, NC = Non Conformity, AC = Corrective Action, AP = Preventive Action, FSCA = Field Safety Corrective Action, FSN = Field Safety Notice, NCA = National Competent Authority, NB = Notified Body, DM = Medical Device, MDR = European Medical Device Regulation (EU) 2017/745.

1. PURPOSE

Purpose of these specifications is to state the obligations and responsibilities related to the distribution activities of Insight Trading SRL (hereinafter called *Distributor*) concerning the medical devices listed in **Annex 1** manufactured by GEM Srl (hereinafter called the *Manufacturer*).

GEM Srl is the "*Manufacturer*" of the medical devices covered by this collaboration, as defined in the European Regulation (EU) 2017/745 and it is therefore responsible for the compliance of the device to the essential requirements listed in Annex I of the mentioned regulation. Therefore, it is responsible for CE marking of these devices, management of corresponding Technical Documentation and maintaining contacts with the Notified Body and Italian Competent Authority (Italian Ministry of Health).

Distributor: any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a device available on the market up until the point of putting into service. The activities of distributors should be deemed to include acquisition, holding and supplying of devices.

Importer: any natural or legal person established within the Union that places a device from a third country on the Union market.

2. PRODUCTS COVERED BY THIS AGREEMENT

The medical devices covered by this agreement are listed in the **Annex 1**. GEM Srl engages to maintain **Annex 1** updates and to send it to the *Distributor* every time it will be re issued for a change in the list of products. The *Distributor* engages to send back a copy of **Annex 1** duly signed for acceptance.

3. GENERAL RESPONSIBILITIES OF THE DISTRIBUTOR (Ref. Art. 14, Reg. (EU) 2017/745)

1.When making a device available on the market, distributors shall, in the context of their activities, act with due care in relation to the requirements applicable.

2.Before making a device available on the market, distributors shall verify that all of the following requirements are met:
(a) the device has been CE marked and that the EU declaration of conformity of the device has been drawn up;
(b) the device is accompanied by the information to be supplied by the manufacturer in accordance with Article 10(11);
(c) for imported devices, the importer has complied with the requirements set out in Article 13(3);
(d) that, where applicable, a UDI has been assigned by the manufacturer.

In order to meet the requirements referred to in points (a), (b) and (d) of the first subparagraph the distributor may apply a sampling method that is representative of the devices supplied by that distributor. 5.5.2017 L 117/27 Official Journal of the European Union EN

Where a distributor considers or has reason to believe that a device is not in conformity with the requirements of this Regulation, it shall not make the device available on the market until it has been brought into conformity, and shall inform the manufacturer and, where applicable, the manufacturer's authorised representative, and the importer. Where the distributor considers or has reason to believe that the device presents a serious risk or is a falsified device, it shall also inform the competent authority of the Member State in which it is established.

3.Distributors shall ensure that, while the device is under their responsibility, storage or transport conditions comply with the conditions set by the manufacturer.

4.Distributors that consider or have reason to believe that a device which they have made available on the market is not in conformity with this Regulation shall immediately inform the manufacturer and, where applicable, the manufacturer's authorised representative and the importer. Distributors shall co-operate with the manufacturer and, where applicable, the manufacturer's authorised representative, and the importer, and with competent authorities to ensure that the necessary corrective action to bring that device into conformity, to withdraw or to recall it, as appropriate, is taken. Where the distributor considers or has reason to believe that the device presents a serious risk, it shall also immediately inform the competent authorities of the Member States in which it made the device available, giving details, in particular, of the non-compliance and of any corrective action taken.

5.Distributors that have received complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device they have made available, shall immediately forward this information to the manufacturer and, where applicable, the manufacturer's authorised representative, and the importer. They shall keep a register of complaints, of non-conforming devices and of recalls and withdrawals, and keep the manufacturer and, where available, the authorised representative and the importer informed of such monitoring and provide them with any information upon their request.

6.Distributors shall, upon request by a competent authority, provide it with all the information and documentation that is at their disposal and is necessary to demonstrate the conformity of a device.

Distributors shall be considered to have fulfilled the obligation referred to in the first subparagraph when the manufacturer or, where applicable, the authorised representative for the device in question provides the required information. Distributors shall cooperate with competent authorities, at their request, on any action taken to eliminate the risks posed by devices which they have made available on the market. Distributors, upon request by a competent authority, shall provide free samples of the device or, where that is impracticable, grant access to the device.

In order to meet the legislative requirements of the Regulation (EU) 2017/745 and to ensure that the medical devices that comply with the legislation are available for supply, it is recommended that the *Distributor* have a quality system in place.

An effective quality system provides assurance that the medical devices that comply with legislative requirements is distributed, that noncompliant, defective or unsuitable medical devices can be detected, that traceability is maintained and that non-conformances and the introduction of changes are controlled. It is strongly recommended a Quality Management System conforming to the requirements of ISO 13485.

4. INVARIABILITY CLAUSES

The *Distributor* cannot make any changes to the Medical Devices covered by this agreement, nor to the instructions sheets, labels, or more generally, to the technical and informational documents of the product, without prior written agreement and approval of the Manufacturer. The devices must be commercialised in the package defined by the Manufacturer and specified in the previous paragraph.

If (as part of the maintenance activities of the manufacturer Quality Management System, management of market surveillance activities, market surveillance, after sales surveillance and post market clinical follow up) it is necessary to make changes to the device, labelling and/or attached information documentation for users (Instructions for use and technical data sheets) , the *Manufacturer* must send a written notice to the *Distributor,* in order to notify such a change, and / or plan a specific technical training action.

The Manufacturer send to the ***Distributor*** a copy of the CE Certifications and Quality Management System Certificate on each new issue or review of the documents concerned, and to communicate their withdrawal, or expiry, in case the *Manufacturer* decides not to proceed with their renewal.

5. TRACEABILITY

The *Distributor* agrees to maintain the traceability of the medical devices, covered by this agreement, in respect of the market and users. This is to allow the *Manufacturer* to withdraw any faulty medical devices (or implement any Field Safety Corrective Action or recall in the market) in case of any non – compliance found and compromising the safety of users and patients. Furthermore, the *Distributor* agrees to cooperate with the Manufacturer in case it is necessary to implement a recall or a Field Safety Corrective Action.

The client traceability must be accomplished by recording the quantity and the lot number of marketed products on the corresponding Transport Document or on a similar document (for example, packing lists or sales invoices).

A copy of this document must be kept by the *Distributor* for a period **of at least 15 years from the date of sale**, in a suitable place to prevent loss or damage. In case of need or request, these documents must be available to the Manufacturer, Notified Body and/or Competent Authority.

Note: the *Distributor* communicate to GEM Srl each time is contacted to make a selling outside of its territory and to ask always if the products are registered in the countries where the eventual exportation is requested.

Records to be maintained by the *Distributor* could include:

- Copies of invoices relating to the receipt and supply of a medical device;
- Copies of orders relating to the receipt and supply of a medical device;
- Records of checks carried (for example labelling checks for CE marks) and the approval of medical devices into saleable stock

If the registrations and the traceability system referred in this Agreement are managed by a software system, the Distributor is responsible for the validation of the programme itself, assuring the back up of the computer data in order to ensure a complete and adequate disaster-recovery.

6. STORAGE AND TRANSPORTATION

The medical devices must be kept under the environmental conditions as shown by the Manufacturer on the label and on the instruction sheet. It is necessary to ensure that the medical device remains in the conditions indicated also with regard to transport to customers. The *Distributor* is required to check, upon delivery of the product, the integrity of the packaging and the absence of damage and pollution.

The device must be stored in the environmental conditions according to what is reported on labelling and Instruction for use in current revision.

Storage conditions must be monitored. The measuring instruments used for checking the environmental conditions of storage of medical devices must be subjected to a plan for checking their calibration status.

The warehouse of the *Distributor* must also be subjected to a periodic cleaning and sanitization programme (Pest Control) as well as to prevent insects, small animals or dirt entering in it.

7. MANAGEMENT OF NON – CONFORMITY

In case of receipt of non – conforming product (damaged, polluted, or degraded packaging, product not corresponding to the order, medical device that does not comply with the agreed specifications, see Annex 2) the *Distributor* shall immediately notify in writing the non – conformity to the *Manufacturer* who has the responsibility to decide the relevant treatment / corrective action and to communicate it, always in writing, to the *Distributor*. Any use "by concession" of non-compliant product, should be authorized exclusively by the *Manufacturer* through the issue of a written notice to the *Distributor* justifying such a decision.

8. MARKET VIGILANCE AND REPORTING

The *Distributor* that have received complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device they have made available, shall immediately forward this information to the *Manufacturer* and, where applicable, to the Importer. The *Distributor* must personally verify all the issues related to the complaint received by visiting the healthcare professionals in order to cooperate with the *Manufacturer* in the investigation phase of the complaint. If the Distributor is not able to collect the necessary information for solving the matter, the *Manufacturer* could go personally to visit the site.

The *Distributor* shall keep a register of complaints, of non – conforming devices and of recalls and withdrawals, and keep the manufacturer and, where available, the Importer informed of such monitoring and provide them with any information upon their request.

The *Distributor* notify the *Manufacturer* of any non – conformity and any incident, which is directly or indirectly aware, found by the user in commercialised devices and coming from the market related to their use.

The notice of the warning received by the *Distributor* to the *Manufacturer* must be carried out to the *Manufacturer* in the shortest possible time taking into account the notification times of the incidents to the European Competent Authorities defined by the Regulation (EU) 2017/745 reported below:

Manufacturer shall report any serious incident immediately after they have established the causal relationship between that incident and their device or that such causal relationship is reasonably possible and not later than **15 days** after become aware of the incident.

In the event of a serious public health threat, the report shall be provided immediately and not later than **2 days** after the manufacturer becomes aware of the threat.

In the event of death or an unanticipated serious deterioration in a person's state of health the report shall be provided immediately after the manufacturer has established or a soon as it suspects a causal relationship between the device and the serious incident but not later than **10 days** after the date on which the manufacturer becomes aware of the serious incident.

Definitions (Ref. European Regulation 2017/745):

Incident: any malfunction or deterioration in the characteristics or performance of a device made available on the market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any undesirable side-effect;

Serious incident: any incident that directly or indirectly led, might have led or might lead to any of the following:
(a) the death of a patient, user or other person,
(b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health,
(c) a serious public health threat;

Serious public health threat: an event which could result in imminent risk of death, serious deterioration in a person's state of health, or serious illness, that may require prompt remedial action, and that may cause significant morbidity or mortality in humans, or that is unusual or unexpected for the given place and time.

The Distributor shall, upon request by a competent authority, provide it with all the information and documentation that is at their disposal and is necessary to demonstrate the conformity of the device. The distributors shall cooperate with competent authorities, at their request, on any action taken to eliminate the risks posed by devices which they have made available on the market. The Distributor, upon request by a competent authority, shall provide free samples of the device or, where that is impracticable, grant access to the device.

8.1 Management of returned medical devices

A medical device should be considered to be a 'return' once it has left the premises of the supplying distributor and is subsequently returned to that premises. This may include the following examples:

- where a distributor supplies a customer with the incorrect medical device, which is subsequently returned
- where a customer returns a medical device to a distributor which they ordered in error
- where a medical device is received back to the premises of a distributor having never been received by the customer (e.g. because the customer's premises was closed)
- where a defective medical device is received back to the premises of a distributor for exchange or repair.

The *Distributor* should be extremely vigilant in their assessment of the suitability of returned medical devices to be placed back into saleable stock. The *Distributor* must be fully confident that the safety and performance of the medical device has not been affected in any way whilst the medical device has been out of their care. Defective devices should be segregated from other stock and identified as defective. When a return is received back it should be placed in a separate area so that there is no risk of it being returned to saleable stock prior to assessment in error. This separate area should be clearly segregated from saleable stock (either by physical means or by a validated computerised system). All stages of the returns process should be documented. This documentation should allow all stages of the returns process to be traced, including the person conducting each stage/activity.

9. POST MARKET SURVEILLANCE

The ***Distributor*** actively cooperates with GEM Srl to monitor the performance and safety of medical devices commercialised and submits periodically this information to the Manufacturer for their evaluation. This activity must be carried out by collecting and transmitting the following data:

- Number of pieces making available on the market;
- Information collected as a result of direct dealings with users of the marketed medical devices;
- Information collected as a result of interviews or questions meant to assess the suitability and safety of the device; sending to the clients of the PMS and PMCF questionnaire to be filled in by the user (See **Annex 5**);
- Information collected as a result of direct dealings with sales agents and any other retailer;
- Information collected as a result of participation in conferences and congresses;
- Claims and warnings received from the market;
- Incident reports;
- Evaluation of similar products marketed by competitors;
- Information notices provided by the Competent Authorities of the countries in which the device is marketed;

10. REGULATORY ASPECTS, REGISTRATION AND TRANSLATIONS

The *Distributor* is responsible for transmitting to the *Manufacturer* the applicable regulatory obligations (in accordance with local and national laws and regulations) in force in the countries in which the device is marketed, in order to allow the *Manufacturer* to prepare the necessary documentation to be shown to local Competent Authority for the registration of the device itself.

Depending on individual cases and specific needs, the *Distributor* can be entrusted by the *Manufacturer,* with maintaining contact with the Competent Authority of countries where the product is marketed for medical devices registration and record keeping (Marketing Authorization and Manufacturer / Facility Registration), notices and incident reports or any Field Safety Corrective Action and recall.

The Distributor sends to the manufacturer a copy of registrations and authorizations issued by the local competent authority, communications and any updates.

The *Manufacturer* is responsible for managing the translation of information material (Instruction sheet, Labelling, Technical data sheet) in the language of the country in which the products are intended to be marketed. The translation must be done by competent personnel with a good knowledge of technical terminology used, depending on the intended use of the device. The *Distributor* verifies the translation and suggests any eventual corrections.

11. AUDITS

Both during the Distributor qualification, and during the subsequent collaboration activities, the Manufacturer reserves the right to carry out inspections at the Distributor facility in order to verify that the requirements of this specification are met. In this case, the verification plan will be communicated and agreed upon with sufficient notice.

12. TRAININGS

The manufacturer GEM Srl periodically organizes training courses for sales agents, distributors and users of medical devices manufactured regarding their technical, chemical, physical and functional specifications, applications for use, surgical techniques and methods of use. This training is organized by GEM Product Specialists.
Depending on the cases, the training will be organized in presence or with "remotely" mode using computer platforms (such as Zoom) that allow the organization of meetings with multiple participants.

The distributor undertakes to ensure the participation of its sales and product managers in the training interventions organized by GEM.

At the end of the training course GEM will send each participant a questionnaire in order to evaluate the effectiveness of the training and its level of learning and knowledge about GEM medical devices specifications. GEM will issue a participation certificate to each participant.

Participation in the initial training courses and subsequent updates is considered by GEM to be an extremely important activity in relation to the knowledge of the characteristics of GEM products, their methods of use, fields of application, warnings and contraindications. The comparison with customers and users is also important in the post-sales surveillance activities since it allows the collection of data to maintain the performance and safety specifications of medical devices.

13. REFERENCE PERSON FOR QUALITY AND REGULATORY ASPECTS

The Distributor undertakes to make available to GEM a person trained on the general requirements of the QMS and of the EU Regulation 2017/745 on medical devices.

This person is: RADULESCU CLAUDIA
Contact: +40 723 284855 / claudia.ignat@gmail.com

14. ANNEXES

Annex 1: List of products
Annex 2: PMS and PMCF form

GEM	SALES SPECIFICATIONS GEM Medical devices	Annex 1

LIST OF MEDICAL DEVICES

Medical device	Code	Packaging
Surgical glue Glubran 2 (monodose vial 1 ml) Surgical glue Glubran 2 (monodose vial 0.5 ml) Surgical glue Glubran 2 (monodose vial 0.25 ml)	G-NB-2 G-NB2-50 G-NB2S-25	10 monodose vials/box
Skin adhesive GLUBRAN Tiss2 (monodose vial 0.5 ml) Skin adhesive GLUBRAN Tiss2 (monodose vial 0.35 ml) Skin adhesive GLUBRAN Tiss2 (monodose vial 0.25 ml)	G-NBOC2 G-NBOC2-35 G-NBOC2-25	10 monodose vials/box
Drop control device	G-DCD-210-8T	Single packaging
Catheter for Laparoscopy Rigid Catheter for Laparoscopy	G2-LPC G2-LPC-RIG	Single packaging
Glutack 25 Glutack 30 Glutack 50 Glutack 60	GB-DS 25 GB-DS 30 GB-DS 50 GB-DS 60	Single packaging
Glutack Short 30 Glutack Short 60	GB-DS SH 30 GB-DS SH 60	Single packaging
Glubran 2 Spray Device Glubran 2 Small spray device Glubran 2 Rigid spray device Glubran 2 Short spray device Glubran 2 Short Small spray device	G2-NBT G2-NBT-SMALL G2-NBT-RIG G2-NBT-SHORT G2NBT-SM SHORT	Single packaging
Dispensing tip	G-DT	Single packaging
1 ml Luer Lock Syringe sterile without needle	G-LLS	Single packaging

Date:	Manufacturer Signature	Distributor Signature	Annex 1 Rev. 01
07.03.2022			

DICHIARAZIONE DI CONFORMITA'
DECLARATION OF CONFORMITY

Fabbricante: *Manufacturer:*	**GEM S.r.l.** Via dei Campi, 2 – 55049 Viareggio (LU) Italy
Dispositivo Medico: *Medical Device:*	**Colla chirurgica Glubran 2** *Surgical Glue GLUBRAN 2*
Classificazione secondo All. IX DDM *Classification Annex IX MDD*	**Classe III - (Regola 8)** *III (Rule 8)*
Percorso di certificazione: *Certification route:*	**Allegato II** (alla Dir. 93/42/CEE emendata dalla Dir. 47/2007) *Annex II (*Dir. 93/42/CEE amending Directive 47/2007)

GEM S.r.l. dichiara che il Dispositivo Medico sopra menzionato è conforme ai Requisiti Essenziali della Direttiva Dispositivi Medici 93/42/CEE consolidata con i requisiti della Dir. 2007/47/EC recepita in Italia con D. Lgs. 37/2010, di cui l'Allegato I, alle norme di prodotto e processo applicabili e alle prescrizioni legislative applicabili ai Legacy Devices di cui all'Art. 120 (3) del Regolamento (UE) 745/2017. Il Fascicolo Tecnico contenente la documentazione pertinente è conservato presso il Fabbricante e messo a disposizione delle Autorità Competenti e dell'Ente Notificato.
GEM S.r.l. ha sviluppato una procedura per la sorveglianza post vendita in accordo alla MEDDEV 2.12/1 e alle disposizioni transitorie previste all'Art.120 (3) del Regolamento (UE) 745/2017 ed è la sola responsabile della presente Dichiarazione di Conformità.

GEM S.r.l. declares that the above mentioned medical device is conforming to the essential requirements of the Medical Device Directive 93/42/CEE consolidated with the requirements of the 2007/47/EC reported in the Annex 1, to the applicable rules of product and process and to transitional provisions of Art. 120 (3) of the Rule (EU) 2017/745. Technical File and supporting documentation are retained under the premises of the Manufacturer at disposition of the Competent Authorities and Notified Body.

GEM S.r.l. has developed an internal procedure for the vigilance system of the medical devices according to MEDDEV 2.12/1 and to transitional provisions of the Art. 120 (3) of the Rule (EU) 745/2017. The manufacturer is the only responsible for this Declaration of Conformity.

Direttive e Leggi applicabili
Applicable Directives and Laws

- DDM 93/42/CEE consolidata dalla Direttiva 47/2007 e recepita in Italia con D. Lgs. 37/2010
- MDR 745/2017 – Art. 120 disposizioni transitorie
- *MDD 93/42/EEC consolidated with the requirements of the Amending Directive 2007/47/EC*
- *MDR 745/2017 – Art. 120 transitional provisions*

Norme europee armonizzate applicabili
Harmonized applicable European standards

Le norme applicabili sono richiamate negli Allegati del corrispondente Fascicolo Tecnico FT 01.
The applicable standards are referenced Annexes of the correspondent Technical File FT 01.

Organismo Notificato: *Notified Body:*	*Istituto Superiore di Sanità* *Viale Regina Elena, 299 – 00161 ROMA Italy*
Nr. Oragnismo Notificato: *Nr. of Notified Body:*	0373
Certificato CE No.: *EC Certificate Nr.:*	**EPG-0242-19 / QCT-0133-19**
Data Certificato CE: *Date of EC Certificate:*	11/07/2019
Data di prima emissione del Certificato: *First emission date of EC Certificate:*	11/07/2019
Scadenza Certificato CE: *EC Certificate expiry date:*	26/05/2024
Validità della presente dichiarazione: *Validity of Conformity Declaration:*	**26/05/2024**

Viareggio, li 17/03/2022

Il Direttore Tecnico: _____
*The Technical Director - **Lodovico Branchetti***

GEM S.r.l.
Via dei Campi, 2 - Tel. +39 0584 389784
55049 - VIAREGGIO (LU) - ITALY
Part. IVA e Cod. Fisc. 01544010463
info@gemitaly.it - www.gemitaly.it

Allegato 1: Elenco codici di vendita
(Annex 1: List of codes for sale)

Dispositivo Medico ***Medical Device***	**Codice** ***Code***	**CND** ***Italian Classification***	**GMDN**	**Nr. di Reg. Banca dati MS; Progressivo di Sistema/ Repertorio – FOR ITALIAN MINISTRY OF HEALTH**
Colla Chirurgica Glubran 2; Sterile in monodose da 1 ml *Surgical Glue GLUBRAN 2; Sterile in 1 ml vials*	G-NB-2	H90010102	58777	15161/R
Colla Chirurgica Glubran 2; Sterile in monodose da 0.5 ml *Surgical Glue GLUBRAN 2; Sterile in 0.5 ml vials*	G-NB2-50	H90010102	58777	306076/R
Colla Chirurgica Glubran 2; Sterile in monodose da 0.25 ml *Surgical Glue GLUBRAN 2; Sterile in 0.25 ml vials*	G-NB2S-25	H90010102	58777	306346/R
Colla Chirurgica Glubran 2; Sterile in monodose da 0.75 ml *Surgical Glue GLUBRAN 2; Sterile in 0.75 ml vials*	G-NB2-75	H90010102	58777	1848839
Colla Chirurgica Glubran 2; Sterile in monodose da 0.60 ml *Surgical Glue GLUBRAN 2; Sterile in 0.60 ml vials*	G-NB2-60	H90010102	58777	1848841
Colla Chirurgica Glubran 2; Sterile in monodose da 0.35 ml *Surgical Glue GLUBRAN 2; Sterile in 0.35 ml vials*	G-NB2-35	H90010102	58777	1848842

CND = Classificazione Nazionale italiana dei Dispositivi medici
GMDN = Global Medical Device Nomenclature

Organismo Notificato 0373
Notified Body 0373

Istituto Superiore di Sanità

Certificato n° *Certificate no.* **QCT-0133-19**

Addendum n° *addendum no.* //-//

Data prima emissione *First issue date*	**11.07.2019**
Data di emissione corrente *Current issue date*	**11.07.2019**
Data di scadenza *Expiry date*	**26.05.2024**

DICHIARAZIONE CE DI CONFORMITA' SISTEMA COMPLETO DI GARANZIA DI QUALITA'

secondo l'Allegato II escluso (4) della Direttiva Europea 93/42/CEE e successive modifiche ed integrazioni.
(recepita in Italia con il D.Lgs. n. 46 del 24.02.1997 e successive modifiche ed integrazioni)

EC DECLARATION OF CONFORMITY FULL QUALITY ASSURANCE SYSTEM

according to Annex II excluding (4) of EC Directive 93/42/EEC and subsequent modifications and integrations.
(transposed in Italy by the D.Lgs. n. 46 issued on 24.02.1997 and subsequent modifications and integrations)

L'Istituto Superiore di Sanità, Organismo Notificato 0373, certifica che il sistema completo di garanzia della qualità attuato da

The Istituto Superiore di Sanità, Notified Body 0373, certifies that the total quality assurance system enforced by

GEM S.r.l.

Sede Legale/** Registered Office: **Via dei Campi, 2 – 55049 Viareggio (LU) ITALIA

per il dispositivo/i

for the device(s)

(vedi allegato tecnico/ see technical sheet)*

è conforme ai requisiti applicabili della Direttiva Europea 93/42/CEE e successive modifiche ed integrazioni.

is in compliance with the applicable requirements of Council Directive 93/42/EEC and subsequent modifications and integrations.

Il Direttore dell'Organismo Notificato
The Director of Notified Body
(Dott.ssa Roberta Marcoaldi)

Roberta Marcoaldi

* **L'allegato tecnico è parte integrante del presente Certificato**
The technical sheet is an integral part of this Certificate.

Organismo Notificato 0373
Notified Body 0373

Istituto Superiore di Sanità

ALLEGATO TECNICO — TECHNICAL SHEET

Il Certificato n° / *The Certificate no.* **QCT-0133-19**

Addendum n° / *addendum no.* //-//

di cui il presente allegato tecnico è parte integrante, è da considerarsi riferito solo al/ai seguente/i prodotto/i soggetto/i a sorveglianza:

of which this technical sheet is an integral part, refers only to the following product(s) that are subject to surveillance:

***Classe III** (Class III)*

Nome prodotto *(Product name)*	***Codice*** *(Code)*
Colla chirurgica Glubran® 2 (Surgical Glue GLUBRAN 2)	*G-NB-2; G-NB2-75; G-NB2-60; G-NB2-50; G-NB2-35; G-NB2S-25*

Valutazione della conformità: vedi MOD-341-01-01 n° 247/19
Conformity assessment: MOD-341-01-01 n. 247/19

Il Direttore dell'Organismo Notificato
The Director of Notified Body
(Dott.ssa Roberta Marcoaldi)

Roberta Marcoaldi

Organismo Notificato 0373
Notified Body 0373

Istituto Superiore di Sanità

Certificato n° *Certificate no.* **EPG-0242-19**

Addendum n° *addendum no.* //-//

Data prima emissione *First issue date* **11.07.2019**
Data di emissione corrente *Current issue date* **11.07.2019**
Data di scadenza *Expiry date* **26.05.2024**

ESAME CE DELLA PROGETTAZIONE DEL PRODOTTO

secondo l'Allegato II (4) della Direttiva Europea 93/42/CEE e successive modifiche ed integrazioni
(recepita in Italia con il D.Lgs. n. 46 del 24.02.1997 e successive modifiche ed integrazioni)

EC DESIGN-EXAMINATION CERTIFICATE

according to Annex II (4) of EC Directive 93/42/EEC and subsequent modifications and integrations
(transposed in Italy by the D.Lgs. n. 46 issued on 24.02.1997 and subsequent modifications and integrations)

L'Istituto Superiore di Sanità, Organismo Notificato 0373, certifica che il fascicolo di progettazione del dispositivo medico

The Istituto Superiore di Sanità, Notified Body 0373, certifies that the design dossier relating to the medical device

(vedi allegato tecnico/ see technical sheet)*

fabbricato da *manufactured by*

GEM S.r.l.

Sede Legale/** Registered Office: **Via dei Campi, 2 – 55049 Viareggio (LU) ITALIA

è stato sottoposto a verifica, conformemente ai requisiti dell'Allegato II (4), della Direttiva Europea 93/42/CEE e successive modifiche ed integrazioni.

has been submitted to verification, according to Annex II (4), of Council Directive 93/42/EEC and subsequent modifications and integrations.

Il Direttore dell'Organismo Notificato
The Director of Notified Body
(Dott.ssa Roberta Marcoaldi)

Roberta Marcoaldi

*** L'allegato tecnico è parte integrante del presente Certificato**
The technical sheet is an integral part of this Certificate.

Organismo Notificato 0373
Notified Body 0373

Istituto Superiore di Sanità

ALLEGATO TECNICO

TECHNICAL SHEET

Il Certificato n°
The Certificate no. **EPG-0242-19**

Addendum n°
addendum no. //-//

di cui il presente allegato tecnico è parte integrante, è da considerarsi riferito solo al/ai seguente/i prodotto/i soggetto/i a sorveglianza:

of which this technical sheet is an integral part, refers only to the following product(s) that are subject to surveillance:

***Classe III** (Class III)*

Nome prodotto *(Product name)*
Colla chirurgica Glubran® 2, sterile *(Surgical Glue GLUBRAN 2, sterile)*

Valutazione della Conformità: MOD-341-01-01 n° 247/19
Conformity assessment: MOD-341-01-01 n. 247/19

Il Direttore dell'Organismo Notificato
The Director of Notified Body
(Dott.ssa Roberta Marcoaldi)

Roberta Marcoaldi