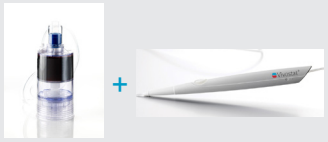
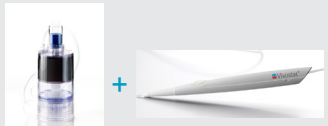
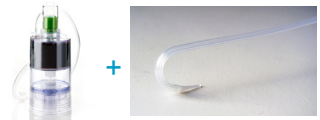
# Vivostat® Product List 2020

| Ref. no. | Product | Units | Illustration |
|---|---|---|---|
| **- Fibrin Set** (Preparation Kit and Application Kit) | | | |
| VS 302 | Fibrin Set | 10 |  |
| VS 312 | Fibrin Set - Concorde | 10 |  |
| VS 322 | Fibrin Set - Co-Delivery | 10 |  |
| VS 323 | Fibrin Set - Endoscopic | 10 |  |
| **- PRF® Set** (Preparation Kit and Application Kit) | | | |
| VS 400 | PRF® Set | 10 |  |
| VS 410 | PRF® Set - Concorde | 10 |  |
| VS 420 | PRF® Set - Endoscopic | 10 |  |
| VS 422 | PRF® Set - Co-Delivery | 10 |  |
| **- Other** | | | |
| VS 510 | Vivostat® Split Kit | 20 |  |

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Location: Moldova
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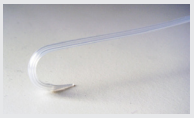
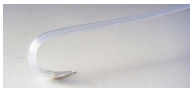
| Ref. no. | Product | Units | Illustration |
|---|---|---|---|
| **- Application Kit** (Including all necessary components for Application) | | | |
| VS 305 | Spraypen® Kit | 4 |  |
| VS 315 | Spraypen® Kit - Concorde | 4 |  |
| VS 325 | Endoscopic Kit[1] | 4 |  |
| VS 335 | Spraypen® Kit - Co-Delivery | 4 |  |
| VS 345 | Endoscopic Kit - Straight[2] | 4 |  |
| VS 355 | Endoscopic Kit - Co-Delivery[1] | 4 |  |
| **- Preparation Kit** (Including all necessary components for Preparation) | | | |
| VS 306 | Fibrin Preparation Kit | 10 |  |
| VS 406 | PRF® Preparation Kit | 10 |  |
| **- Durables** | | | |
| APL 400 | Applicator Unit | 1 |  |
| APL 404 | Applicator Unit Co-Delivery[3] | 1 |  |
| PRO 800 | Processor Unit | 1 |  |

[1] Only to be used together with VS 220 - Endoscopic Applicator Handle
[2] Can be used together with VS 220 and scope solutions such as Bronchoscope, Arthroscope, Laparoscope etc.
[3] All applications need to be controlled with the Vivostat® Foot Switch, VS 222

| Ref. no. | Product | Units | Illustration |
|---|---|---|---|
| VS 220 | Endoscopic Applicator Handle | 1 |  |
| VS 222 | Foot switch | 1 |  |
| **- Installation and Demonstration Kit** | | | |
| VS 280 | Installation Kit | 1 |  |
| VS 290 | Demonstration Kit | 1 |  |

Vivostat®

# DECLARATION OF CONFORMITY

Issue date: 2024-09-19 | Previous issue date: 2023-06-29

Vivostat operates a full quality assurance system in accordance with Annex II of the Medical Devices Directive 93/42/EEC, + Amendment directive 2007/47/EEC.

We, the manufacturer, hereby declare, under our sole responsibility, that the products as listed below are in conformity with the provisions of the Directive 93/42/EEC, amended by Directive 2007/47/EEC.

This is to confirm that the Vivostat® System complies with the Essential Requirements as laid down in Annex I of the Medical Devices Directive.

The devices are manufactured by or for: Vivostat A/S, Borupvang 2, 3450 Alleroed, Denmark

Notified body:
- Identification no.: 0477
- Name: Eurofins Product Testing Italy Srl

This Declaration of Conformity includes the following devices:

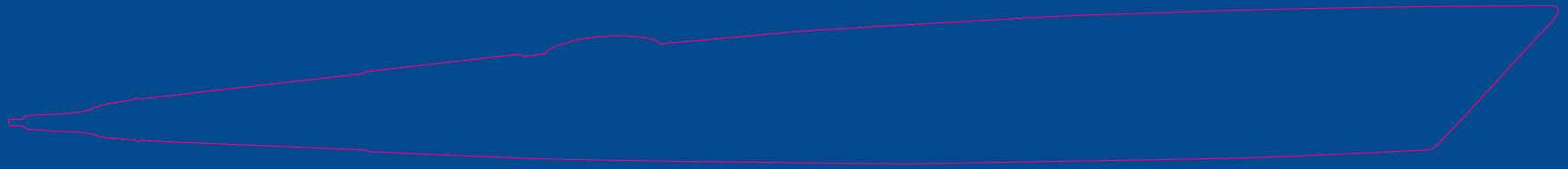
| Device purpose | Device trade name | Ref. no. | Class | Rule (Annex IX) | Date CE Marking was first applied |
|---|---|---|---|---|---|
| Preparation | Vivostat Fibrin Preparation kit | VS 306 | III | Rule 13/17 | 2003-06-19 |
| | Vivostat PRF Preparation kit | VS 406 | III | Rule 13/17 | 2003-06-19 |
| | ArthroZheal® Preparation Kit | AZ 506 | III | Rule 13/17 | 2022-02-28 |
| | Vivostat processor PRO 800 | PRO 800 | IIa | Rule 2/3 | 2010-09-29 |
| | Vivostat processor PRO 800 Compact | PRO 800-5 | IIa | Rule 2/3 | 2024-09-18 |
| Application | Vivostat Spraypen kit | VS 305 | IIa | Rule 2 | 2001-05-17 |
| | Vivostat Spraypen kit Concorde | VS 315 | IIa | Rule 2 | 2003-08-13 |
| | Vivostat Endoscopic kit | VS 325 | IIa | Rule 6 | 2002-05-08 |
| | Vivostat Endoscopic kit – straight | VS 345 | IIa | Rule 6 | 2002-05-08 |
| | Vivostat Split kit | VS 510 | IIa | Rule 2 | 2014-04-24 |
| | Vivostat applicator APL 400 | APL 400 | IIa | Rule 11 | 2010-09-29 |
| Co-Delivery | Vivostat Spraypen kit Co-delivery | VS 335 | IIa | Rule 2 | 2003-06-19 |
| | Vivostat Endoscopic kit – Co-delivery | VS 355 | IIa | Rule 6 | 2002-05-08 |
| | Vivostat applicator APL 404 | APL 404 | IIa | Rule 11 | 2010-09-29 |
| Procedure Sets | Vivostat Fibrin Set | VS 302 | III | Combination | 2003-06-19 |
| | Vivostat Fibrin Set – Concorde | VS 312 | III | Combination | 2003-06-19 |
| | Vivostat Fibrin Set – Co-delivery | VS 322 | III | Combination | 2003-06-19 |
| | Vivostat Fibrin Set – Endoscopic | VS 323 | III | Combination | 2003-06-19 |
| | Vivostat PRF Set | VS 400 | III | Combination | 2003-06-19 |
| | Vivostat PRF Set – Concorde | VS 410 | III | Combination | 2003-06-19 |
| | Vivostat PRF Set – Endoscopic | VS 420 | III | Combination | 2003-06-19 |
| | Vivostat PRF Set – Co-delivery | VS 422 | III | Combination | 2003-06-19 |
| | Vivostat Obsidian ASG | GM 700 | III | Combination | 2003-06-19 |
| | Vivostat Obsidian ASG – Endo | GM 720 | III | Combination | 2018-02-20 |
| | Vivostat Obsidian RFT | GM 740 | III | Combination | 2018-02-20 |
| | ArthroZheal® Set | AZ 500 | III | Combination | 2022-02-28 |
| | ArthroZheal® Set – Endoscopic | AZ 520 | III | Combination | 2022-02-28 |

The Preparation Kits, the Application Kits and the Procedure Sets contain the following components under mutual compatibility declaration under article XII of Medical Devices Directive 93/42/EEC, + Amendment directive 2007/47/EEC;

- Vasuflo Scalp Vein Set, Ref no. 40018, CE0123
- B.Braun Needle, 21G, Ref no. 4657527, CE0123
- B.Braun Medical Replacement Cap, Ref no. 474900, CE0123
- RoweSpike II, Ref no. A-6425, CE0482
- Ovesco Fistula Brush, Ref no. 200.65, CE0124
- BD Microlance 3, Ref no. 300637. CE0050

On behalf of Vivostat A/S:

Marko M. Rackovic, CEO



Vivostat®

*Fibrin*


A revolution in fibrin sealant technology

Vivostat®
Fibrin

# A revolution in fibrin sealant technology

In approx. 24 minutes the fully automated Vivostat® system prepares 5-6 ml of autologous fibrin sealant from 120 ml of the patient's own blood

Compared to conventional sealant products, Vivostat® Fibrin Sealant offers a multitude of benefits to both the patient and the surgeon:

- **Excellent safety profile and high biocompatibility**
  Vivostat® Fibrin Sealant is derived from the patient's own blood and as such it demonstrates excellent biocompatibility. Unlike conventional products, which are most often based on single donor blood, pooled blood or bovine components (e.g. aprotinin), Vivostat® Fibrin Sealant does not contain any exogenous thrombin or bovine components. The autologous nature of Vivostat® efficiently eliminates the risks of bovine or human-borne contaminants. This is the only way to protect the patient and the surgeon against viral diseases not yet identified.

- **Unique and versatile application devices**
  The wide selection of application devices provide the surgeon with unparalleled freedom in the use of fibrin sealant throughout surgery. The application devices can be used intermittently during the entire surgical procedure without experiencing the blockage that is common in conventional systems. Furthermore, Vivostat® Fibrin Sealant can be applied at very close range allowing for pinpoint application, and rapid polymerisation ensures that the fibrin remains where it is applied.

- **Superior physical properties**
  Clinical studies and comparative tests have demonstrated that Vivostat® Fibrin Sealant is superior to conventional fibrin sealants on important parameters such as time to haemostasis, elasticity, adhesion to tissue and impact on tissue[1,2].

## The Vivostat® system is designed with emphasis on user-friendliness

You will find the system straightforward and easy to use. It can easily be moved between operating theatres if required. Furthermore, the innovative Danish design makes the system easy to operate, maintain and clean.

1) Comparative kinetics of polymerisation of three fibrin sealants and influence on timing of tissue adhesion · Kjaergard H K et al. · Thrombosis Research 2000; 98: 221-228
2) The Vivostat® application system: A comparison with conventional fibrin sealant application systems · Dodd R A, Cornwell R et al. · Technology and Health Care 2002; 10: 401-411


COMPLETE
REMOVE PREP UNIT

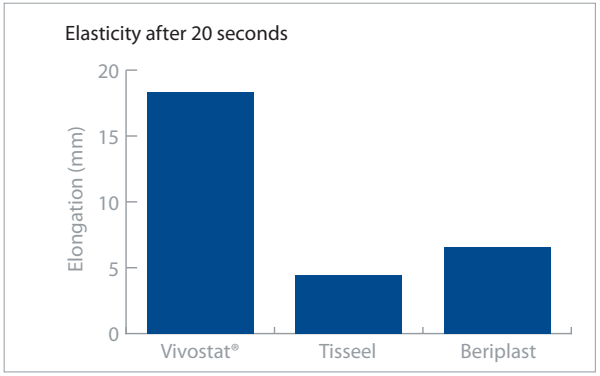
Vivostat®
Fibrin

# Vivostat® Fibrin Sealant has excellent properties

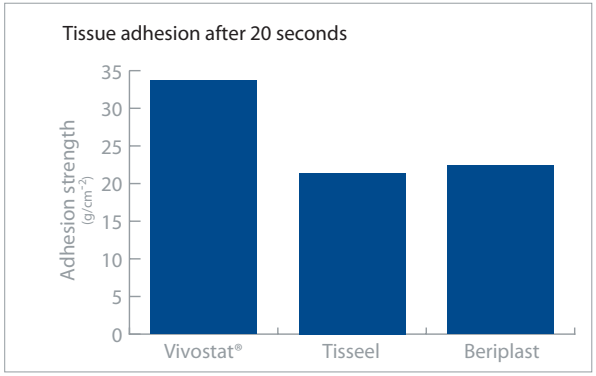
Clinical studies and comparative tests have demonstrated that Vivostat® Fibrin Sealant outperforms other fibrin sealants on important parameters such as time to haemostasis, elasticity, adhesion to tissue and impact on tissue

In order to evaluate and compare the clinically important physical and adhesive properties of Vivostat® Fibrin Sealant, a series of in-vitro rheologicals, tensile tests and ex-vivo tissue adhesion models were developed[1].

The five parameters that are most important for the efficacy of surgical sealants have been tested and compared with two conventional fibrin sealants, Tisseel® from Baxter and Beriplast® from CSL Behring (distributed by Takeda).

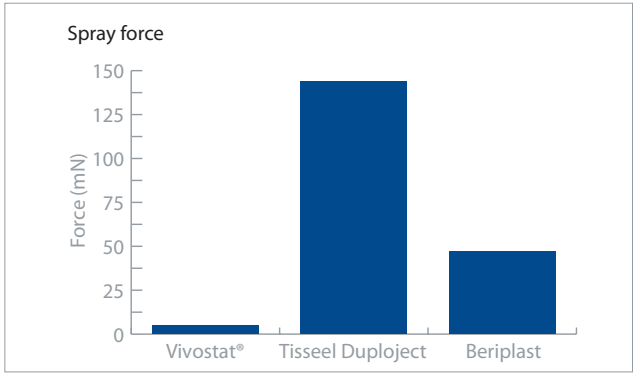


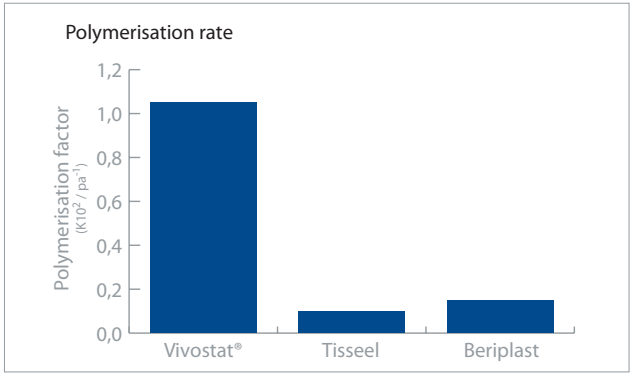

**Elasticity**
Surgical sealants must be very flexible to move with the tissue. This is especially important in thoracic procedures as the sealant is often applied when the lung is partly deflated. Most compounds have an inverse relationship between strength and elasticity. Comparative tests have, however, shown Vivostat® Fibrin Sealant to be extremely flexible[2], more than three times as flexible as conventional products while maintaining sufficient strength.

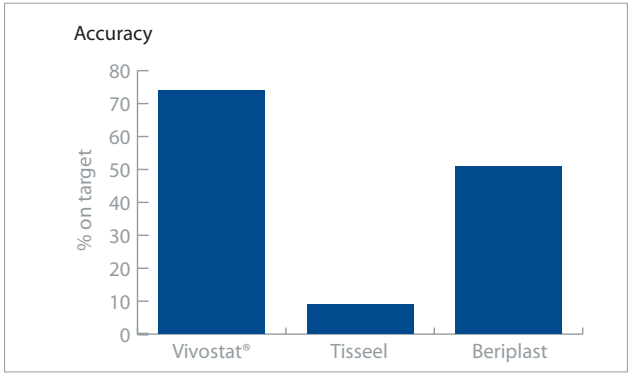



**Adhesion**
Numerous products focus on the tensile strength of the sealant, but neglect the most important parameter of adhesion to tissue. Provided that the internal strength of the sealant and the tissue itself are sufficiently high, it is the sealant:tissue adhesive strength that is the determining factor for tissue:tissue joint failure. The graph shows adhesion strength at first break and clearly demonstrates the superior performance of Vivostat® Fibrin Sealant[2].

1) Development of a model for measurement of adhesion strength of fibrin sealant to human tissue · Kjaergard H K et al. · European Surgical Research 1999; 31: 491-496
2) Comparative kinetics of polymerisation of three fibrin sealants and influence on timing of tissue adhesion · Kjaergard H K et al. · Thrombosis Research 2000; 98: 221-228




**Impact on tissue**
All designers of spray systems face a challenge as they want to minimise disruption or damage to the tissue caused by the high flow rate of the propellant. The Vivostat® system solves this problem with the unique design of the application devices and the Applicator Unit, which provides efficient mixing and imparts very low forces on the tissue. The graph shows the spray force (impact on the tissue) 5 cm from the nozzle[3].

**Time to haemostasis**
An efficient sealant needs to polymerise quickly in order to build up its internal strength and provide a rapidly effective barrier. The polymerisation of Vivostat® Fibrin Sealant is activated by a simple pH change and does not require an enzymic reaction. Polymerisation rates are therefore much faster than conventional sealants based on fibrinogen/thrombin[2]. Vivostat® Fibrin Sealant obtains 80% of its full strength within only 1 minute.

**Accuracy**
The ability to accurately place the fibrin sealant increases the efficiency (faster haemostasis, rapid sealing etc.) and enables the surgeon to make better use of the fibrin that is available. Accuracy is most important in pinpoint application, in difficult to reach areas and small anastomoses. The graph shows the relative amount of fibrin that reaches a target area of 2 $cm^2$ at the manufacturer's recommended spray distance[3].

3) The Vivostat® application system: A comparison with conventional fibrin sealant application systems · Dodd R A, Cornwell R et al. · Technology and Health Care 2002; 10: 401-411

# The Vivostat® system

The Vivostat® process is fully automated, and because of the straightforward and intuitive handling it is easy to operate by the healthcare personnel

The uniqueness of the Vivostat® system is a novel patented biotechnological process that enables reliable and reproducible preparation of autologous fibrin sealant without using cryoprecipitation and without the need for a separate thrombin component.

The fully automated Vivostat® system consists of three components:

- **Disposable Set**
  The single-use set contains all components needed for preparation and application of Vivostat® Fibrin Sealant. It is available with a range of application devices each optimised for different surgical procedures.
- **Processor Unit**
  The Processor Unit is used to process the patient's blood and prepare the fibrin solution.
- **Applicator Unit**
  The Applicator Unit controls the delivery of fibrin sealant to the surgical site and offers a number of different spray modes. The Co-Delivery Applicator, furthermore, allows drugs or cells to be co-delivered with Vivostat® Fibrin Sealant.

The Processor Unit can be placed in any room or corridor in the surgical department. It is often placed centrally in the department to supply multiple operating theatres. It can, however, easily be moved between operating theatres if required.

The Applicator Unit is positioned outside the sterile field in the operating theatre. The integrated microprocessor technology automatically primes the application device and the large display informs the surgeon of the remaining volume of fibrin sealant at all times.

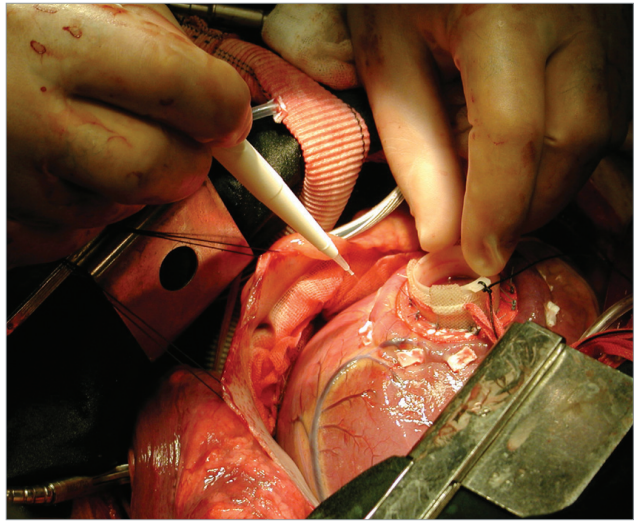
The Vivostat® Applicator Unit and Processor Unit

Vivostat®
Fibrin

# Three easy steps to prepare Vivostat® Fibrin Sealant

**1. Draw blood from the patient**
At the time of surgery or up to 24 hours before, citrate (supplied with the kit) is added to the Preparation Unit. 120 ml of the patient's own blood is then drawn into the same unit.


**2. Process the patient's blood**
The Preparation Unit is placed in the Processor Unit. At the touch of a button the process starts; after approx. 24 minutes, an autologous fibrin solution is ready for use. No thrombin or bovine components are added to the blood or fibrin sealant at any time.



**3. Load the Applicator Unit and spray**
The fibrin solution is easily loaded into the Applicator Unit and applied to the surgical site using one of the unique application devices (e.g. the Spraypen).

Vivostat®
Fibrin

# Application devices for all situations

The Vivostat® system offers a variety of different disposable application devices. They are designed for the delivery of fibrin sealant to the surgical site in a precise and targeted manner, without experiencing the blockage that is common in conventional sealant systems

Each application device has been developed using the knowledge of specialised surgeons to improve product performance. The application devices are used in conjunction with the Applicator Unit and are all based upon the well-known Vivostat® microspray technology. The Applicator Unit continually displays the volume of fibrin sealant available and allows the surgeon to choose from a number of different spray modes to carefully control the delivery of fibrin to the surgical site.


**Spraypen Kit (also in a Co-Delivery version)**
The Vivostat® Spraypen is a central and unique component of the Vivostat® system. It enables the surgeon to apply Vivostat® Fibrin Sealant accurately and intermittently throughout the entire procedure.

**Endoscopic Kit-Straight**
The Vivostat® Endoscopic Kit-Straight allows the application of Vivostat® Fibrin Sealant in multiple different endoscopic solutions e.g. Colonoscopes, Bronchoscopes, Laparoscopes or Gastroscopes and it can be used to treat fistulas.

**Endoscopic Kit (also in a Co-Delivery version)**
The Vivostat® Endoscopic Kit is used in various types of Minimally Invasive Surgery. The single-use endoscopic application catheter is easily loaded into the endoscopic handle, which is inserted via a 5 mm trocar. The pre-bent spraytip enables the surgeon to manipulate the tip and spray in multiple directions.


5.3 ml
HIGH
Vivostat®

Vivostat® Fibrin

# Vivostat® Co-Delivery

Vivostat has developed the revolutionary Co-Delivery system that makes it possible to co-deliver a desired substance (drugs, cells etc.) with Vivostat® Fibrin Sealant

The opportunities with the Vivostat® Co-Delivery system are vast and the system allows the surgeon to apply a selected substance easily and effectively. Furthermore, it may be possible to reduce the total cost of a procedure by using the Vivostat® Co-Delivery system[1].

Options for Co-Delivery include:

**Drugs**
- Antimicrobials
- Chemotherapeutics
- Pain medications

**Cells**
- Stem cells
- Skin cells

Co-delivering drugs, stem cells etc. with the Vivostat® Fibrin Sealant solution offers the surgeon and the patient a number of benefits:

- Topical application
- Targeting affected/desired area
- Possible higher local dose
- Possible lower systemic impact
- Improved compliance

Moreover, no thrombin is added to Vivostat® Fibrin Sealant (unlike most other sealants). This is beneficial to the Co-Delivery system as thrombin activation has been shown to have a negative effect on cell survival.

The fibrin membrane found in Vivostat® Fibrin Sealant has, furthermore, been shown to postpone the degradation process of the substance. This means that the fibrin membrane ensures a slow and sustained release of the substance offering a prolonged effect[2].

**How does it work**

It is possible to co-deliver more than 5 ml of substance together with Vivostat® Fibrin Sealant. The substance is applied using one of the different Vivostat® Co-Delivery application devices, which enables the surgeon to apply the substance accurately and intermittently throughout the entire procedure. The substance and the Vivostat® Fibrin Sealant is mixed as it leaves the tip of the application device and polymerises immediately upon application - this way the substance stays where it is intended to act.

1) Use of autologous bone marrow cells concentrate enriched with platelet-rich fibrin on cortico-cancellous bone allograft for posterolateral multilevel cervical fusion Vadalà et al. · Journal of Tissue Engineering and Regenerative Medicine 2008; 2: 515–520.

2) Intrapleural topical application of cisplatin with the surgical carrier Vivostat increases the local drug concentration in an immune-competent rat model with malignant pleuromesothelioma · Lardinois et al. · Journal of Thoracic and Cardiovascular Surgery.2006;131:697-703


Vivostat® Fibrin Sealant
Vivostat® Fibrin Sealant is used for the preparation and application of autologous fibrin sealant from only 120 ml of the patient's own blood. The sealant does not contain any exogenous thrombin or bovine components
Vivostat® Fibrin
Vivostat® Fibrin

Vivostat®
Fibrin

# Frequently asked questions

## Can I draw less than 120 ml blood

The system and the preparation process are designed based on this specific volume. A reduction in blood volume will reduce the amount of fibrin sealant. The Preparation Unit should therefore always be completely filled with 120 ml of blood.

## Can I use plasma if I cannot draw blood

Yes, this is a viable option for paediatric or anaemic patients. We recommend patients should weigh more than 20 kg to draw 120 ml blood. The Vivostat® system operates in exactly the same way with plasma. There are just a few important things to remember:

- It must be fresh frozen plasma
- You cannot use products such as SAG M or other erythrocyte products. They will not produce any fibrin as the plasma has been removed.

## Can I use blood from the heart-lung machine

Yes, you can take blood from the heart-lung machine. To make sure that the priming fluid and blood is fully mixed, we recommend to wait 10 minutes after the patient has been connected to the heart-lung machine before drawing the blood.

## When should I draw the 120 ml blood from the patient

We recommend to draw blood when the patient is anaesthetised or up to four hours before the operation. However, there is nothing in the design or process of the Vivostat® system that prevents you from drawing blood earlier. You can fill the Preparation Unit up to 24 hours before you place it in the Processor Unit. If the blood is drawn more than four hours before use in the Processor Unit, the Preparation Unit should be kept in the refrigerator at 5 degrees C (do not freeze). In addition, labelling and storage procedures must be established.

## For how long can I use Vivostat® Fibrin Sealant

Vivostat® Fibrin Sealant can be prepared and used intermittently throughout a lengthy operation without loss of effectiveness. Studies have shown that storage of Vivostat® fibrin solution for eight hours at room temperature after preparation has no significant effect on the physical properties of the derived sealant.

## Can I use Vivostat® fibrin sealant when the patient is fully heparinised

Vivostat® Fibrin Sealant will perform very well on fully heparinised patients and on patients on aspirin and warfarin therapy.

Vivostat®
Fibrin

# Ideas have come to life

The Vivostat® idea was conceived in 1992 by a group of Danish researchers searching for a simple and fully automated way of preparing fibrin sealant, onsite and from the patient's own blood

Following the initial development phase, the idea was further matured in co-operation with specialists from across the world, and in 2001, the first generation of the Vivostat® Fibrin Sealant product was launched by the Danish company Vivolution A/S (now Vivostat A/S).

Today, the Vivostat® technology comprises more than autologous fibrin sealant. The advanced blood processing technology has been further developed and a wide range of Vivostat® products are used on a daily basis in numerous surgical departments and wound care centres across Europe and Asia. The idea has come to life!

**Vivostat PRF®**

Vivostat PRF® (Platelet Rich Fibrin) solves the problems of conventional PRP systems (platelet rich plasma) by leveraging the revolutionary Vivostat® Fibrin Sealant blood processing technology.

By combining a platelet concentrate with a fibrin sealant solution, it is possible to have a carrier, a controlled release and a medium for vascular ingrowth – all in one product, Vivostat PRF®.

From 120 ml blood, 5-6 ml of Vivostat PRF® can be prepared, with 7 times the platelet level of the donor's blood – corresponding to a platelet level above 1 million platelets/µl. Unlike conventional PRP systems, the instant polymerisation of the fibrin ensures that the growth factors remain precisely where they are applied.

For more information about Vivostat PRF® or Vivostat® Fibrin Sealant and their areas of use please visit **www.vivostat.com** or call +45 8880 8400

Vivostat®
*Fibrin*

Vivostat A/S
Borupvang 2
DK-3450 Alleroed
Denmark

Tel. +45 8880 8400
Fax +45 4582 4800

info@vivostat.com
www.vivostat.com

# Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

| | |
|---|---|
| Manufacturer name | Vivostat A/S |
| Manufacturer address and contact details | Borupvang 2, 3450 Alleroed, Denmark |
| Single Registration Number (SRN) (if available) | DK-MF-000019521 |

| | |
|---|---|
| Authorised Representative name (if applicable) | Cecilie Hurup Munkbøl |
| Authorised Representative address and contact details | Borupvang 2, 3450 Alleroed, Denmark |
| Single Registration Number (SRN) (if available) | N/A |

| | |
|---|---|
| Notified body name (if applicable) | Eurofins Product Testing, Italy |
| Notified body number (if applicable) | 0477 |
| Directive Certificate number(s)<br>to which this confirmation is made (if applicable) | EPT 0477.MDD.21/4373<br>EPT 0477.MDD.21/4374<br>EPT 0477.MDD.21/4375<br>EPT 0477.MDD.21/4376<br>EPT 0477.MDD.21/4377 + COMMUNICATION |
| Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable) | 2024-05-06 |
| End date of extended validity/transition period | 2027-12-31 (certain products)<br>2028-12-31 (certain other products) |

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

  *Choose applicable statements:*

  ☐ Expired *before* 20 March 2023:

  ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or

  ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or

  ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

  *Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:*

  ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

  ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

  X Expired/expires *after* 20 March 2023:

  *Choose one applicable statement:*

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

x Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

*Choose one applicable statement:*

x Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Quality Management System (QMS)**

*Choose one applicable statement:*

x A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.
☐ A QMS in accordance with Article 10(9) MDR is in place.
☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

➢ **Device(s) as listed in the attached schedule**

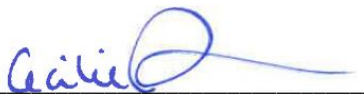
- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

**Signed for and on behalf of the manufacturer:**

Full Company Name: Vivostat A/S

Location & Date: Cary, North Carolina, 2024-08-09

Signature,



Print Name, Title: Cecilie Hurup Munkbøl, QA/RA Manager, PRRC and Management Respresentative

Contact Details (at least email): chm@vivostat.com

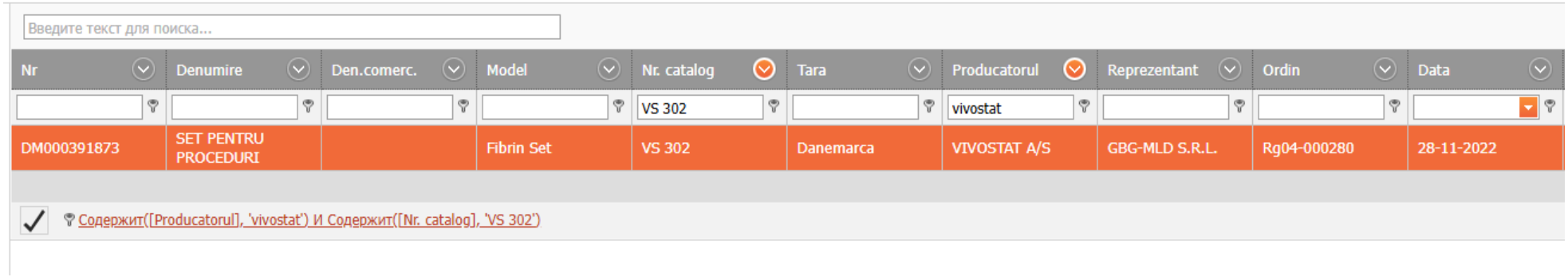
## Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the medical device | | Medical device classification according to Regulation EU 2017/745 | CE certificate number issue under Directive 93/42/EEC (MDD) EPT 0477.MDD | Emission date of the CE certificate MDD | Expire date of the CE certificate MDD | Name and number of the notified body | End of extension date requested | Substitute Device(s) (if applicable) |
|---|---|---|---|---|---|---|---|---|
| Nome | Reference n. / ID | | | | | | | |
| Vivostat® Fibrin Preparation kit | VS 306 | Class III | Cert. No.: 4377 | 2003-06-19 | 2024-05-26 | Eurofins Product Testing Italy S.r.l, 0477 | 2027-12-31 | NA |
| Vivostat® PRF Preparation kit | VS 406 | Class III | Cert. No.: 4377 | 2003-06-19 | 2024-05-26 | Eurofins Product Testing Italy S.r.l, 0477 | 2027-12-31 | NA |
| Vivostat® ArthroZheal Preparation kit | AZ 506 | Class III | Cert. No.: 4377 | 2022-02-28 | 2024-05-26 | Eurofins Product Testing Italy S.r.l, 0477 | 2027-12-31 | NA |
| Vivostat® Processor Unit PRO 800 | PRO 800 | Class IIa | Cert. No.: 4374 | 2010-09-29 | 2024-05-27 | Eurofins Product Testing Italy S.r.l, 0477 | 2028-12-31 | NA |
| Vivostat® Processor Unit PRO 800 Compact | PRO 800-5 | Class IIa | Cert. No.: 4374 | 2024-05-22 | 2024-05-27 | Eurofins Product Testing Italy S.r.l, 0477 | 2028-12-31 | NA |
| Vivostat® Spraypen kit | VS 305 | Class IIa | Cert. No.: 4375 | 2001-05-17 | 2024-05-27 | Eurofins Product Testing Italy S.r.l, 0477 | 2028-12-31 | NA |
| Vivostat® Spraypen kit, Concorde | VS 315 | Class IIa | Cert. No.: 4375 | 2003-08-13 | 2024-05-27 | Eurofins Product Testing Italy S.r.l, 0477 | 2028-12-31 | NA |
| Vivostat® Endoscopic kit | VS 325 | Class IIa | Cert. No.: 4375 | 2002-05-08 | 2024-05-27 | Eurofins Product Testing Italy S.r.l, 0477 | 2028-12-31 | NA |
| Vivostat® Endoscopic kit – Straight | VS 345 | Class IIa | Cert. No.: 4375 | 2002-05-08 | 2024-05-27 | Eurofins Product Testing Italy S.r.l, 0477 | 2028-12-31 | NA |
| Vivostat® Split kit | VS 510 | Class IIa | Cert. No.: 4375 | 2014-04-24 | 2024-05-27 | Eurofins Product Testing Italy S.r.l, 0477 | 2028-12-31 | NA |
| Vivostat® Applicator Unit APL 400 | APL 400 | Class IIa | Cert. No.: 4373 | 2010-09-29 | 2024-05-26 | Eurofins Product Testing Italy S.r.l, 0477 | 2028-12-31 | NA |
| Vivostat® Spraypen kit – Co-delivery | VS 335 | Class IIa | Cert. No.: 4375 | 2003-06-19 | 2024-05-27 | Eurofins Product Testing Italy S.r.l, 0477 | 2028-12-31 | NA |
| Vivostat® Endoscopic kit – Co-delivery | VS 355 | Class IIa | Cert. No.: 4375 | 2002-05-08 | 2024-05-27 | Eurofins Product Testing Italy S.r.l, 0477 | 2028-12-31 | NA |
| Vivostat® Applicator Unit APL 404 | APL 404 | Class IIa | Cert. No.: 4373 | 2010-09-29 | 2024-05-26 | Eurofins Product Testing Italy S.r.l, 0477 | 2028-12-31 | NA |
| Vivostat® Fibrin Set | VS 302 | Class III | Cert. No.: 4377 | 2003-06-19 | 2024-05-27 | Eurofins Product Testing Italy S.r.l, 0477 | 2027-12-31 | NA |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Vivostat® Fibrin Set – Concorde | VS 312 | Class III | Cert. No.: 4377 | 2003-06-19 | 2024-05-26 | Eurofins Product Testing Italy S.r.l, 0477 | 2027-12-31 | NA |
| Vivostat® Fibrin Set – Co-delivery | VS 322 | Class III | Cert. No.: 4377 | 2003-06-19 | 2024-05-26 | Eurofins Product Testing Italy S.r.l, 0477 | 2027-12-31 | NA |
| Vivostat® Fibrin Set – Endoscopic | VS 323 | Class III | Cert. No.: 4377 | 2003-06-19 | 2024-05-26 | Eurofins Product Testing Italy S.r.l, 0477 | 2027-12-31 | NA |
| Vivostat® PRF Set | VS 400 | Class III | Cert. No.: 4377 | 2003-06-19 | 2024-05-26 | Eurofins Product Testing Italy S.r.l, 0477 | 2027-12-31 | NA |
| Vivostat® PRF Set – Concorde | VS 410 | Class III | Cert. No.: 4377 | 2003-06-19 | 2024-05-26 | Eurofins Product Testing Italy S.r.l, 0477 | 2027-12-31 | NA |
| Vivostat® PRF Set – Endoscopic | VS 420 | Class III | Cert. No.: 4377 | 2003-06-19 | 2024-05-26 | Eurofins Product Testing Italy S.r.l, 0477 | 2027-12-31 | NA |
| Vivostat® PRF Set – Co-delivery | VS 422 | Class III | Cert. No.: 4377 | 2003-06-19 | 2024-05-26 | Eurofins Product Testing Italy S.r.l, 0477 | 2027-12-31 | NA |
| Vivostat® Obsidian ASG® | GM 700 | Class III | Cert. No.: 4377 | 2018-02-20 | 2024-05-26 | Eurofins Product Testing Italy S.r.l, 0477 | 2027-12-31 | NA |
| Vivostat® Obsidian ASG® - Endo | GM 720 | Class III | Cert. No.: 4377 | 2018-02-20 | 2024-05-26 | Eurofins Product Testing Italy S.r.l, 0477 | 2027-12-31 | NA |
| Vivostat® Obsidian RFT® | GM 740 | Class III | Cert. No.: 4377 | 2018-02-20 | 2024-05-26 | Eurofins Product Testing Italy S.r.l, 0477 | 2027-12-31 | NA |
| Vivostat® ArthroZheal® | AZ 500 | Class III | Cert. No.: 4377 | 2022-02-28 | 2024-05-26 | Eurofins Product Testing Italy S.r.l, 0477 | 2027-12-31 | NA |
| Vivostat® ArthroZheal® Endo | AZ 520 | Class III | Cert. No.: 4377 | 2022-02-28 | 2024-05-26 | Eurofins Product Testing Italy S.r.l, 0477 | 2027-12-31 | NA |
| Vivostat® Endoscopic Applicator Handle | VS 220 | Class Ir | Self declare | 2001-05-17 | NA | NA | NA | NA |
| Obsidian ASG® Endoscopic Applicator Handle | GM 220 | Class Ir | Self declare | 2018-03-02 | NA | NA | NA | NA |
| ArthroZheal® Endoscopic Applicator Handle | AZ 220 | Class Ir | Self declare | 2022-02-28 | NA | NA | NA | NA |

# REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

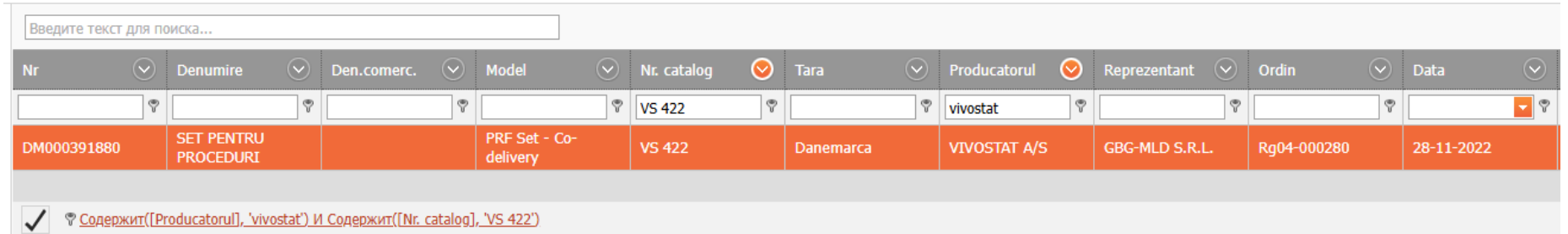


Введите текст для поиска...

| Nr | Denumire | Den.comerc. | Model | Nr. catalog | Tara | Producatorul | Reprezentant | Ordin | Data |
|---|---|---|---|---|---|---|---|---|---|
| | | | | VS 302 | | vivostat | | | |
| DM000391873 | SET PENTRU PROCEDURI | | Fibrin Set | VS 302 | Danemarca | VIVOSTAT A/S | GBG-MLD S.R.L. | Rg04-000280 | 28-11-2022 |

Содержит([Producatorul], 'vivostat') И Содержит([Nr. catalog], 'VS 302')

# REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE



Введите текст для поиска...

| Nr | Denumire | Den.comerc. | Model | Nr. catalog | Tara | Producatorul | Reprezentant | Ordin | Data |
|---|---|---|---|---|---|---|---|---|---|
| | | | | VS 422 | | vivostat | | | |
| DM000391880 | SET PENTRU PROCEDURI | | PRF Set - Co-delivery | VS 422 | Danemarca | VIVOSTAT A/S | GBG-MLD S.R.L. | Rg04-000280 | 28-11-2022 |

Содержит([Producatorul], 'vivostat') И Содержит([Nr. catalog], 'VS 422')

eurofins | Product Testing

CP MDR.MOD.005a.04 - 08.01.2024

To Cecilie Hurup Munkbøl
**Vivostat A/S**
Borupvang 2,
3450 Alleroed, Denmark
Email: chm@vivostat.com

# Conferma ordine / *Order confirmation* - Confirmation letter

**Letter Reference: 23Q02002 COVer.01**

| | |
|---|---|
| **Confermiamo con la presente dello stato di una domanda formale e di un accordo scritto nell'ambito del Regolamento UE 2017/745 modificato dal Regolamento (UE) 2023/607 per quanto riguarda le disposizioni transitorie per alcuni dispositivi medici**<br><br>La presente lettera conferma che, Eurofins Product Testing Italy Srl, Organismo Notificato (NB) designato ai sensi del Regolamento (UE) 2017/745 (MDR) e identificato con il numero NB0477, ha ricevuto una domanda formale in conformità alla sezione 4.3, primo comma, dell'allegato VII dell'MDR e ha firmato un accordo scritto in conformità alla sezione 4.3, secondo comma, dell'allegato VII dell'MDR con il seguente fabbricante: | ***Confirmation of the status of a formal application and written agreement in the framework of Regulation EU 2017/745 amending by Regulation (EU) 2023/607 as regards the transitional provisions for certain medical devices***<br><br>*This letter confirms that, Eurofins Product Testing Italy Srl designated against Regulation (EU) 2017/745 (MDR) and identified by the number NB0477, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:* |

| | | |
|---|---|---|
| **Azienda /** *Company* | **Vivostat A/S** | |
| **Sede Legale /** *Registered Office* | Borupvang 2, 3450 Alleroed, Denmark | |
| **Contratto n° /** *Contract No.* | 23-11-000021 | |
| **SRN** | DK-MF-000019521 | |
| **Quotazione /** *Quotation* | **Progetto N° /** *Project No.* | 23Q02002 |
| | **Emessa in data /** *Issue date* | 20/02/2023 |
| | **Firmata e timbrata per accettazione in data /** *Stamped and signed for acceptance on date* | 15/03/2023 |
| **Riferimento normativo /** *Regulatory reference* | Regolamento (UE) 2017/745 (MDR)<br>☒ Allegato IX(I) / *Annex IX(I),*<br>☒ Allegato IX(II) / *Annex IX(II),*<br>☐ Allegato X / *Annex X*<br>☐ Allegato XI(A) / *Annex XI(A)*<br>☐ Allegato XI(B) / *Annex XI(B)* | |
| **in relazione alla richiesta di certificazione:** *for the following certification request* | ☒ **iniziale /** *initial* ☐ **sorveglianza /** *surveillance* ☐ **rinnovo /** *renewal*<br>☐ **subentro /** *transfer* ☐ **revisione /** *revision* ☐ **estensione /** *extension* | |
| **Dispositivi Medici /** *Medical Devices* | Vedi tabella di seguito riportata con i dispositivi oggetto di incarico /<br>*See table below with the medical device list included in the order.* | |

| | |
|---|---|
| I dispositivi coperti dalla domanda formale e dall'accordo scritto di cui sopra sono elencati nella Tabella 1 di seguito. | *The devices covered by the formal application and the written agreement mentioned above are listed in Table 1 below.* |
| Il fabbricante ha rilasciato specifica dichiarazione in data 22/07/2024 con richiesta di utilizzo della proroga di cui al Regolamento UE 2023/607 nella quale precisa che sono soddisfatte le condizioni di accesso alla proroga stessa. | *The manufacturer has issued a specific declaration on 22/07/2024 requesting the use of the extension provided for in EU Regulation 2023/607 in which it specifies that the conditions for access to the extension are met.* |
| I tempi di transizione che si applicano ai dispositivi oggetto della presente lettera (vedi Tabella 1) e che sono di seguito riportati, permangono a condizione che il fabbricante continui a rispettare le altre condizioni specificate nell'articolo 120.3c della MDR (come modificato dal Regolamento UE 2023/607):<br>• 26 Maggio 2026 per i dispositivi impiantabili su misura di Classe III<br>• 31 Dicembre 2027 per i dispositivi di Classe III e per i dispositivi impiantabili di Classe IIb, escluse le suture, graffette, otturazioni dentali, apparecchi ortodontici, corone dentali, viti, cunei, placche, fili, perni, clip e connettori<br>• 31 Dicembre 2028 per dispositivi di Classe IIb che non ricadono nel punto precedente, per i dispositivi di Classe IIa e Classe I immessi sul mercato in condizioni di sterilità o con funzione di misurazione.<br>• 31 Dicembre 2028 per i dispositivi che non richiedono l'intervento di un organismo notificato ai sensi della MDD ma che lo richiedono ai sensi della MDR (ad esempio, i dispositivi di classe I che si qualificano come strumenti chirurgici riutilizzabili). | *The transition timelines that apply to the devices covered by this letter (see Table 1) and that are shown below, are valid if the manufacturer continues compliance to the other conditions specified in Article 120.3c of MDR (as amended by Regulation EU 2023/607):*<br>• *26 May 2026 for Class III custom-made implantable devices*<br>• *31 December 2027 for Class III devices and Class IIb implantable devices excluding sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors*<br>• *31 December 2028 for devices Class IIb other than those covered by the above point, devices of Class IIa, and devices of Class I placed on the market in sterile condition or have a measuring function*<br>• *31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)* |

## Tabella 1: Dispositivi inclusi nella presente comunicazione
## *Table 1: Devices covered by this letter*

| **Nome del dispositivo /** *Device name*<br>*Basic UDI-DI*<br>*(*se presente *– if applicable)* | **Classificazione MDR**<br>*MDR Device classification*<br>(come proposta dal fabbricante e verificata al pre application stage / *as proposed by the manufacturer and verified at the pre-application stage*) | **Se il dispositivo MDR è un dispositivo sostitutivo, identificazione del dispositivo MDD corrispondente**<br>*If the MDR device is a substitute device, identification of the corresponding MDD device* | **Riferimento del certificato MDD dei dispositivi oggetto della richiesta MDR e identificazione NB**<br>*MDD Certificate Reference(s) of the devices under MDR application and the NB identification* |
|---|---|---|---|
| Vivostat applicator APL 400,<br>Vivostat applicator APL 404<br>(ref. APL-400, APL-404) | IIa | N/A | Certificate n°: EPT 0477.MDD.21/4373;<br>NB 0477 Eurofins Product testing Italy |
| Vivostat processor PRO 800,<br>Vivostat processor PRO 800 Compact<br>(ref. PRO-800, PRO 800-5) | IIa | N/A | Certificate n°: EPT 0477.MDD.21/4374;<br>NB 0477 Eurofins Product testing Italy |
| Vivostat application kit:<br>Vivostat Spraypen kit,<br>Vivostat Spraypen kit Concorde,<br>Vivostat Spraypen kit Co-delivery,<br>Vivostat Endoscopic kit,<br>Vivostat Endoscopic kit – straight,<br>Vivostat Endoscopic kit – Co-delivery,<br>Vivostat Split kit<br>(ref. code VS 305, VS 315, VS 325, VS 335, VS 345, VS 355, VS 510) | IIa | N/A | Certificate n°: EPT 0477.MDD.21/4375;<br>NB 0477 Eurofins Product testing Italy |
| Vivostat PRF Preparation kit/set:<br>Vivostat PRF Preparation kit,<br>Vivostat PRF Set,<br>Vivostat PRF Set – Concorde,<br>Vivostat PRF Set – Endoscopic,<br>Vivostat PRF Set – Co-delivery,<br>ArthroZheal<br>(ref. code VS 406, VS 400, VS 410, VS 420, VS 422, AZ506, AZ520, AZ500); | III | N/A | Certificate n°: EPT 0477.MDD.21/4376;<br>Certificate n°: EPT 0477.MDD.21/4377;<br>NB 0477 Eurofins Product testing Italy<br><br>Communication n°<br>EPT.0477.MDD.22/GP0030<br>NB 0477 Eurofins Product testing Italy |

| | | | |
|---|---|---|---|
| Vivostat Fibrin Preparation kit/set:<br>Vivostat Fibrin Preparation kit,<br>Vivostat Fibrin Set,<br>Vivostat Fibrin Set – Concorde,<br>Vivostat Fibrin Set – Co-delivery,<br>Vivostat Fibrin Set – Endoscopic<br>(ref. code VS 306, VS 302, VS 312, VS 322, VS 323);<br>Vivostat Obsidian set:<br>Vivostat Obsidian ASG,<br>Vivostat Obsidian ASG – Endo,<br>Vivostat Obsidian RFT<br>(ref. code GM700, GM 720, GM 740) | | | |
| Vivostat Endoscopic Applicator Handle,<br>Obsidian ASG Endoscopic Applicator Handle,<br>ArthroZheal Endoscopic Applicator Handle<br>(ref. code VS220, GM 220, AZ 220) | Ir | N/A | Not applicable - Class I according to MDD |

| | |
|---|---|
| Con riferimento al Vostro ordine per il progetto di certificazione secondo il Regolamento UE 2017/745 di cui ai riferimenti sopra citati:<br>• si conferma la nostra accettazione dello stesso; | *With reference to your order for the certification project in accordance with the information listed above:*<br>• *we confirm our acceptance of the contract;* |
| • l'incarico di Certificazione ai sensi del Regolamento UE 2017/745 con la presente è stato perfezionato e ha efficacia agli effetti del punto 4.3 dell'Allegato VII del Regolamento (UE) 2017/745, avendo svolto l'attività di "Application Review"; | • *the engagement of Certification in accordance with Regulation (EU) 2017/745 has hereby been perfected and is effective for the purposes of Section 4.3 of Annex VII of Regulation (EU) 2017/745, having carried out the "Application Review" activity;* |
| • come precisato dal Regolamento UE 2023/607 l'organismo notificato che ha rilasciato il certificato secondo la direttiva 93/42/CEE continua a essere responsabile dell'appropriata sorveglianza dei requisiti applicabili relativi ai dispositivi che ha certificato. | • *as specified by EU Regulation 2023/607 the notified body that issued the certificate according to Directive 93/42/EEC continues to be responsible for the appropriate monitoring of the applicable requirements for the devices it has certified.* |
| Tenuto conto che Eurofins Product Testing Italy Srl è l'ON che ha rilasciato i certificati secondo la direttiva 93/42/CEE e specificati nella tabella 1 di cui sopra, si precisa che continuerà a svolgere le attività di sorveglianza per tali dispositivi. | *Taking into account that Eurofins Product Testing Italy Srl is the ON that has issued the certificates according to Directive 93/42/EEC and specified in Table 1 above, it is hereby specified that it will continue to carry out surveillance activities.* |

Le condizioni e le modalità economiche sono indicate nell'offerta di Eurofins Product Testing Italy Srl **n° 23Q02002 del 20/02/2023** da Voi timbrata e controfirmata per accettazione.
Il programma di tale attività sarà concordato con gli esperti tecnici che Vi contatteranno nei prossimi giorni.
Nel caso in cui riteniate un motivato e documentabile caso di conflitto di interessi, in relazione ad uno o più esperti, è Vostra facoltà sollevare una riserva scritta entro 7 giorni.
L'annullamento o lo spostamento della data di intervento (qualora prevista) che verrà concordata dovrà essere segnalato al Eurofins Product Testing Italy Srl con almeno 5 (cinque) giorni lavorativi di preavviso.

*The general terms and the economic conditions as well as the quotation are indicated in the quotation **n° 23Q02002 of the 20/02/2023** signed.*
*The activities dates are scheduled from the office of Eurofins Product Testing Italy S.r.l. of Torino (Italy).*
*In case you suspect a justified and documentable case of conflict of interest, in relation of the inspectors, you may raise a written reserve within 7 days.*
*The cancellation or displacement of the intervention date (if any) which will be agreed upon must be communicated to Eurofins Product Testing Italy Srl with at least (five) working days notice.*

**Indice delle revisioni -** *Revision History*

| **Data /** *Date* | **Descrizione /** *Action* |
|---|---|
| 06/08/2024 | Prima emissione / *Initial issue* |
| 18/09/2024 | Seconda emissione per inserimento delle seguenti referenze: Vivostat processor PRO 800 Compact (ref. PRO 800-5), ArthroZheal (ref. code AZ506, AZ520, AZ500) e precisazione dei seguenti codici: ref. APL-400, APL-404, VS220, GM 220, AZ 220 / *Second issue to add the following references: Vivostat processor PRO 800 Compact (ref. PRO 800-5), ArthroZheal (ref. code AZ506, AZ520, AZ500) and specify the following codes: APL-400, APL-404, VS220, GM 220, AZ 220* |

**Eurofins Product Testing Italy Srl**
*Firma / Signature*

Paolo Trisoglio
Managing Director

Data / *Date* 18/09/2024