Vivostat®

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Date: 2025.01.31 10:30:43 EET
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Location: Moldova
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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) to which this confirmation is made (if applicable)	EPT 0477.MDD.21/4373 EPT 0477.MDD.21/4374 EPT 0477.MDD.21/4375 EPT 0477.MDD.21/4376 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) 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**

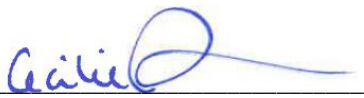
- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

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