

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 Allerød, Denmark

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

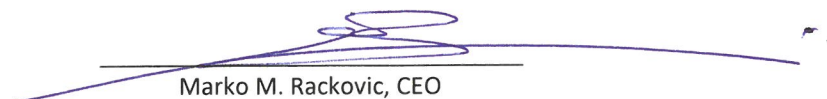
This Declaration of Conformity includes the following devices:

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	Ila	Rule 2/3	2010-09-29
	Vivostat processor PRO 800 Compact	PRO 800-5	Ila	Rule 2/3	2024-09-18
Application	Vivostat Spraypen kit	VS 305	Ila	Rule 2	2001-05-17
	Vivostat Spraypen kit Concorde	VS 315	Ila	Rule 2	2003-08-13
	Vivostat Endoscopic kit	VS 325	Ila	Rule 6	2002-05-08
	Vivostat Endoscopic kit – straight	VS 345	Ila	Rule 6	2002-05-08
	Vivostat Split kit	VS 510	Ila	Rule 2	2014-04-24
	Vivostat applicator APL 400	APL 400	Ila	Rule 11	2010-09-29
Co-Delivery	Vivostat Spraypen kit Co-delivery	VS 335	Ila	Rule 2	2003-06-19
	Vivostat Endoscopic kit – Co-delivery	VS 355	Ila	Rule 6	2002-05-08
	Vivostat applicator APL 404	APL 404	Ila	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