DECLARATION OF CONFORMITY

Issue date: 2022-06-07 Previous issue date: 2022-05-06

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

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

This Declaration of Conformity includes the following devices:

Device purpose	Device trade name	Ref. no.	Classi-fication	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
	Vivostat® ArthroZheal Preparation Kit	AZ 506	III	Rule 13/17	2022-02-28
	Vivostat® Processor Unit PRO 800 Series	PRO 800	IIa	Rule 2/3	2010-09-29
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 Unit APL 400 Series	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 Unit APL 404 Series	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	2018-02-20
	Vivostat® Obsidian ASG® - Endo	GM 720	III	Combination	2018-02-20
	Vivostat® Obsidian RFT®	GM 740	III	Combination	2018-02-20
	Vivostat® ArthrozHeal®	AZ 500	III	Combination	2022-02-28
	Vivostat® ArthrozHeal®- Endo	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/EC;

- 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

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On behalf of Vivostat A/S:

Sven Lange, CEO