

MEDINOVITAS Kft.

Gyógyászati Eszköz és Gyógyszerkereskedelmi Kft.

4220 Hajdúböszörmény, Külső-Hadházi út 10.

Tel.: + 36 52 561 339 – Fax: + 36 52 561 927

www.medinovitas.eu E-mail: medinovitas@medinovitas.eu

Adószám: 10556997-2-09



Messrs.

Fra Production S.p.A

Via delle Poste, 16

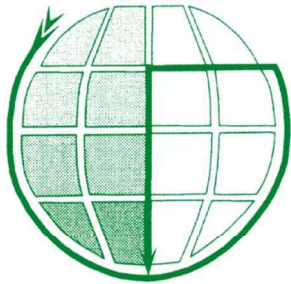
14010 Dusino San Michele (AT)

Italy

EU DECLARATION OF CONFORMITY

MEDINOVITAS Kft (SRN code HU-MF-000007416), with headquarters in Külső Hadházi utca 10, 4220 - Hajdúböszörmény (Hungary), as manufacturer of the following medical devices:

Denomination	Codes	Basic UDI-DI
Surgifix Compribend P 2020	02123228	599957142M0304010103ZS
	02123229	599957142M0304010103ZS
Surgifix Autofix Haft	02121530	599957142M0303010201ZA
	02121531	599957142M0303010201ZA
	02121532	599957142M0303010201ZA
	02121533	599957142M0303010201ZA
	02121534	599957142M0303010201ZA
	02121535	599957142M0303010201ZA
	02121536	599957142M0303010201ZA
	02121537	599957142M0303010201ZA
Sugifix Autofix Haft latex free	02121551	599957142M0303010201ZA
	02121552	599957142M0303010201ZA
	02121553	599957142M0303010201ZA
	02121554	599957142M0303010201ZA
	02121555	599957142M0303010201ZA
	02121556	599957142M0303010201ZA
	02121557	599957142M0303010201ZA
	02121558	599957142M0303010201ZA
Surgifix Autofix Haft XL latex free	02121545	599957142M0303010201ZA
	02121546	599957142M0303010201ZA
	02121547	599957142M0303010201ZA
	02121548	599957142M0303010201ZA
	02121549	599957142M0303010201ZA
	02121550	599957142M0303010201ZA
Surgifix bende Ideal	00490058	599957142M0303010101Z5
	00490119	599957142M0303010101Z5
	00490107	599957142M0303010101Z5
	00490120	599957142M0303010101Z5
	00490108	599957142M0303010101Z5



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Denomination	Codes	Basic UDI-DI
Surgifix bende Ideal	00490060	599957142M0303010101Z5
	00490121	599957142M0303010101Z5
	00490103	599957142M0303010101Z5
	00490109	599957142M0303010101Z5
	00490122	599957142M0303010101Z5
	00490110	599957142M0303010101Z5
	00490123	599957142M0303010101Z5
	00490111	599957142M0303010101Z5
	00490124	599957142M0303010101Z5
	00490112	599957142M0303010101Z5
	00490067	599957142M0303010101Z5

Intended for the fixation of the dressing, the light support and containment of small traumas and the light support of dressings, all of them risk class I, in accordance with rule 1 of Annex VIII of EU Regulation 2017/745, declares under its total exclusive responsibility, that such devices:

- comply with the general safety and performance requirements and the provisions of Regulation (EU) 2017/745 and subsequent amendments, as per the Technical Files archived at the company;
- Common Specifications for device compliance have not been used;
- they are manufactured in accordance with the Technical Files, which satisfy the requirements set out in Annex II + III of the aforementioned Regulation.

Hajdúböszörmény 21.03.2025

The legal representative

Jeney Sándor

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