EU DECLARATION OF CONFORMITY

According to Annex IV to (EU) 2017/745 Regulation on medical devices

We,

HOIST MEDICAL SAS
23 Bis Quai de Rive Neuve 13007 Marseille
+33 4 91 76 73 29 - www.hoist-medical.com

SRN: FR-MF-000026140

Guarantee and declare under our sole responsibility that the device:

STOMAFIT™ STOMA STOPPER

CODE	DESIGNATION	BASIC UDI-DI
STxx-xxx	STOMAFIT™ STOMA STOPPER	376034811100.05B3

Invasive medical device class I non sterile intended for Stoma closure prevention between devices changes pursuant to Rule 5 of Chapter III of Appendix VIII to (EU) 2017/745 Regulation Complies with the applicable requirements of (EU) 2017/745 Regulation and the French Public Health Code.

This declaration shall be based on the elements provided in the technical file of the device demonstrating compliance with the essential requirements of (EU) 2017/745 Regulation

Effective date: November 19th 2024
Expiry date : November 18th 2029

Marseille, November 19th 2024

Bernard DAURELLE, CEO

