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:

STARFIT™ ENFit® MEDICINE DOSE AID

CODE	DESIGNATION	BASIC UDI-DI
MF01	ENFit® MEDICINE DOSE AID	376043811400.12C9

Invasive medical device class I non sterile pursuant to Rule 5 of Chapter III of Appendix VIII to (EU) 2017/745 Regulation , intended to allow administering oral doses directly into patients' mouths with ENFit enteral syringes; 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: January 20th 2025
Expiry date : January 19th 2030

Marseille, January 20th, 2025

Bernard DAURELLE, CEO and PRRC

