EU DECLARATION OF CONFORMITY

According to the appendix IV of (EU) 2017/745 Regulation related to the 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 medical device:

STARFIT™ ENFit® MALE FEMALE CAP

CODE	DESIGNATION	BASIC UDI
MFCAP	ENFit® MALE FEMALE CAP	376034811400.10C3

Non-invasive medical device class Is intended for securing the ENFit® nutrition syringe pursuant to rule 2 of chapter III of appendix VIII of (EU) 2017/745 Regulation
Complies with the applicable requirements of (EU) 2017/745 Regulation and the French Public Health Code.

Notified body involved:
Name: DQS Medizinprodukte GmbH
Addresses: August-Schanz-Straße 21
60433 FRANKFURT AM MAIN Germany
Number: 0297
Assessment Evaluation Procedure: Annex IX (conformity assessment based on a quality management system and on assessment of technical documentation)

Certificate number: 551177 MDR2017Q

EMDN CODE: A070501

Common specifications: No common specifications are used in relation to which conformity is declared

Marseille, November 1st, 2024

Bernard DAURELLE, CEO and PRRC