EU Quality Management Certificate

This is to certify that the company

HOIST-MEDICAL

23 Quai de rive neuve
7e Arrondissement
13007 Marseille
France

SRN: FR-MF-000026140

has established, implemented and maintains a Quality Management System in accordance with

Annex IX, Chapter I and III of the Regulation (EU) 2017/745

Conformity Assessment based on a Quality Management System and on Assessment of Technical Documentation

for the device categories and products listed in the Annex of this certificate.

The conformity of the Quality Management System has been verified in an audit and is subject to regular surveillance in accordance with Annex IX, Chapter 1, Section 3.
Limitations to this certificate are listed in the Annex.

Devices listed in the Annex may bear the CE marking with the identification number of the Notified Body (0297).

For placing of devices of class III and devices class IIb implantable according to Article 52(4) subparagraph 2 listed in the Annex on the market, an additional certificate according to Annex IX, Chapter II is required.

Certificate registration no.	551177 MDR2017Q
Certificate ID	1000217799
Effective date	2025-02-14
Expiry date	2029-10-31
Frankfurt am Main,	2025-02-14

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-094

DQS Medizinprodukte GmbH

Heinrich von Mettenheim
Managing Director

Accredited Body: DQS Medizinprodukte GmbH, August-Schanz-Str. 21, 60433 Frankfurt am Main
DQS Medizinprodukte GmbH is a Notified Body according to Regulation (EU) 2017/745 of the Council concerning medical devices with the Identification Number 0297.
The validity of the certification can only be verified by the QR-code.

420.90 Version 7.0

Annex to EU Quality Management Certificate
SRN of Manufacturer: FR-MF-000026140
Certificate ID: 1000217799

Device categories and variants covered by this certificate:

Device category:	**MDN1202 - Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis**
Product name:	STARFIT NASOGASTRIC FEEDING TUBE
Risk classification:	IIa
Basic-UDI-DI:	376034811200.01B8
Intended purpose:	Nasogastric enteral feeding

Device category:	**MDN1202 - Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis**
Product name:	STARFIT NASOGASTRIC FEEDING TUBE WITH GUIDEWIRE
Risk classification:	IIa
Basic-UDI-DI:	376034811200.02BA
Intended purpose:	Nasogastric enteral feeding

Device category:	**MDN1202 - Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis**
Product name:	STARFIT NASOGASTRIC FEEDING AND ASPIRATION TUBE
Risk classification:	IIa
Basic-UDI-DI:	376034811200.06BJ
Intended purpose:	Nasogastric enteral feeding

Device category:	**MDN1202 - Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis**
Product name:	STARFIT NASOGASTRIC FEEDING AND ASPIRATION TUBE WITH GUIDEWIRE
Risk classification:	IIa
Basic-UDI-DI:	376034811200.07BL
Intended purpose:	Nasogastric enteral feeding

Device category:	**MDN1202 - Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis**
Product name:	STARFIT NASOGASTRIC FEEDING TUBE WEIGTHED WITH GUIDEWIRE
Risk classification:	IIa
Basic-UDI-DI:	376034811200.03BC
Intended purpose:	Nasogastric enteral feeding

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Device category:	**MDN1202 - Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis**
Product name:	STARFIT NASOGASTTRIC FEEDING TUBE WITH BOLUS AND GUIDEWIRE
Risk classification:	IIa
Basic-UDI-DI:	376034811200.04BE
Intended purpose:	Nasogastric enteral feeding

Device category:	**MDN1202 - Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis**
Product name:	STARFIT NASOGASTTRIC FEEDING TUBE WEIGTHED WITH BOLUS AND GUIDEWIRE
Risk classification:	IIa
Basic-UDI-DI:	376034811200.05BG
Intended purpose:	Nasogastric enteral feeding

Device category:	**MDN1202 - Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis**
Product name:	STARFIT ENTERAL MILK STRAW
Risk classification:	Is
Basic-UDI-DI:	376034811400.02C4
Intended purpose:	Transfer milk from a bottle to an ENFit syringe

Device category:	**MDN1202 - Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis**
Product name:	STARFIT ENTERAL SAMPLING STRAW
Risk classification:	Is
Basic-UDI-DI:	376034811400.03C6
Intended purpose:	Transfer liquid from a bottle to an ENFit syringe

Device category:	**MDN1202 - Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis**
Product name:	STARFIT ENTERAL NEEDLE STRAW
Risk classification:	Is
Basic-UDI-DI:	376034811400.04C8
Intended purpose:	Transfer liquid from a bottle to an ENFit syringe

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Device category:	**MDN1202 - Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis**
Product name:	STARFIT BOTTLE ADAPTOR XL STARFIT BOTTLE ADAPTOR L STARFIT BOTTLE ADAPTOR M STARFIT BOTTLE ADAPTOR S STARFIT BOTTLE ADAPTOR XS STARFIT UNIVERSAL BOTTLE ADAPTOR
Risk classification:	Is
Basic-UDI-DI:	376034811400.06CC
Intended purpose:	Adaptor to allow transfer of liquids from bottle to a straw or syringe

Device category:	**MDN1202 - Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis**
Product name:	STARFIT ENTERAL 3 WAYS STOPCOCK
Risk classification:	Is
Basic-UDI-DI:	376034811400.08CG
Intended purpose:	Allow nasogastric tube rinsing

Device category:	**MDN1202 - Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis**
Product name:	STAFIT ENFit MALE CAP
Risk classification:	Is
Basic-UDI-DI:	376034811400.07CE
Intended purpose:	Secure Enteral devices

Device category:	**MDN1202 - Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis**
Product name:	STARFIT ENFit MALE FEMALE CAP
Risk classification:	Is
Basic-UDI-DI:	376034811400.10C3
Intended purpose:	Allow a male female connection for enteral devices

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Device category:	**MDN1202 - Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis**
Product name:	STAFIT ENTERAL EXTENSION 150 Cm STAFIT ENTERAL EXTENSION 75 Cm
Risk classification:	IIa
Basic-UDI-DI:	376034811400.01C2
Intended purpose:	Allow connection between feeding tube and food containers

Device category:	**MDN1202 - Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis**
Product name:	PURFIT GASTROSTOMY BUTTON
Risk classification:	IIb
Basic-UDI-DI:	376034811100.01AT
Intended purpose:	Gastrostomy feeding button

Device category:	**MDN1202 - Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis**
Product name:	PURFIT GASTROSTOMY EXTENSION UNIVERSAL GASTROSTOMY EXTENSION
Risk classification:	IIa
Basic-UDI-DI:	376034811100.02AV
Intended purpose:	Allow connection between feeding button and food containers

Examinations and tests performed:
551177_A213290MED_01_dated 2023-08-22
551177_A214252MED_03_dated 2023-08-22
551177_A213290MED_04_dated 2025-01-25

Further conditions for or limitations to the validity of the certificate:
In case of products that are placed on market in sterile condition, the involvement of the Notified Body in the conformity assessment procedure is limited to the aspects of manufacture concerned with securing and maintaining sterile condition

Reference to previous certificates:

Revision	Date of Issue	Certificate-ID	Description of change
01	2024-11-01	100033594	Addition of PURFIT Gastrostomy Button and Accessories