Hoist medical	**TECHNICAL DATA SHEET ENTERAL FEEDING ACCESSORIES / FICHE TECHNIQUE ACCESSOIRES DE NUTRITION ENTERALE**	REVISION : FV-03 DATE : 20/01/2025

Device description

Trade Name: **STARFIT™**

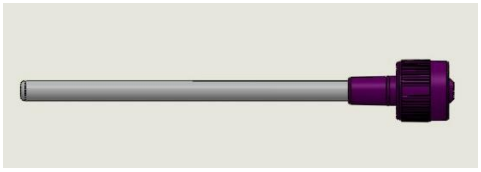
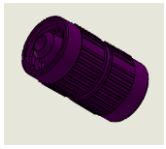
Device Category (MDN Code)

MDN1202 (Non-active non implantable devices)

European Medical Device Nomenclature (EMDN Code)

G0280 (Nasogastric Tubes Accessories)

General description:

MS01  Milk Straw	SS01  Sampling Straw	NS01  Needle Straw
MC XX  Male Cap	MFCAP  Male Female Cap	NGE-XX  Extension
BA –X 01  Bottle Adaptor	UBA 01  Universal Bottle Adaptor	SK01  3 Ways Stopcock
MF01  Medicine Dose Aid	MFS01  Medicine Dose Straw	TR01  Male Male Transfer Connector
BR01  Enteral Brush		

Code	Accessory	Designation	Description
MS01	Milk Straw	STARFIT™ ENTERAL MILK STRAW	PVC tubing with ENFit® connector to allow transfer of milk from a bottle to an enteral syringe
MS01WB		STARFIT™ ENTERAL MILK STRAW WIDE BORE	
SS01	Sampling Straw	STARFIT™ ENTERAL SAMPLING STRAW	PVC tubing with ENFit® connector to allow transfer of liquid from a bottle to an enteral syringe
NS01	Needle Straw	STARFIT™ ENTERAL NEEDLE STRAW	Blunt needle with ENFit® connector to allow of liquid from a bottle to an enteral syringe
MC01	Male Cap	STARFIT™ MALE CAP	ENFit® male cap for enteral device securing
MC15		STARFIT™ MALE CAP (15/BOX)	
MC50		STARFIT™ MALE CAP (50/BOX)	
MFCAP	Male Female Cap	STARFIT™ MALE FEMALE CAP	ENFit® male female cap
NGE-75	Extension	STARFIT™ NASOGASTRIC EXTENSION SET 75 cm	PVC tubing with ENFit® male and female connectors to allow connexion between feeding devices and food containers
NGE-150		STARFIT™ NASOGASTRIC EXTENSIO SET 150 cm	
BA-XS01	Bottle Adaptor	STARFIT™ BOTTLE ADAPTOR XS 15-16.5 mm	Bottle adaptor for transferring liquids to an enteral syringe
BA-S01		STARFIT™ BOTTLE ADAPTOR S 18-19.5 mm	
BA-M01		STARFIT™ BOTTLE ADAPTOR M 18.5-20.5 mm	
BA-L01		STARFIT™ BOTTLE ADAPTOR L 20-21.5 mm	
BA-XL01		STARFIT™ BOTTLE ADAPTOR XL 25.5-27 mm	
UBA-01		STARFIT™ UNIVERSAL BOTTLE ADAPTOR 14.5-27.5 mm	
SK01	3 Ways Stopcock	STARFIT™ ENTERAL 3 WAYS STOPCOK	3 Ways Stopcock to be connected with enteral feeding devices to allow rinsing feeding tubes without dismantling extensions
MF01	Medicine Dose Aid	STARFIT™ Medicine Dose Aid	Ergonomic and comfortable dosing nipple for administering oral doses directly into patients' mouths with ENFit enteral syringes
MFS01	Medicine Dose Straw	STARFIT™ Medicine Dose Straw	Dosing of medicines administered directly into

			the patient's cheek or back of the mouth
TR01	Male Male Transfer Connector	STARFIT™ Male Male Transfer Connector	ENFit Male/Male connector for medicines transfer between enteral ENFit syringes
BR01	Enteral Brush	Enteral Cleaning Brush	Enteral Cleaning Brush

Devices Classification

Code	Designation	Product class
MS01	STARFIT™ ENTERAL MILK STRAW	I sterile
MS01WB	STARFIT™ ENTERAL MILK STRAW WIDE BORE	
SS01	STARFIT™ ENTERAL SAMPLING STRAW	
NS01	STARFIT™ ENTERAL NEEDLE STRAW	
MC01	STARFIT™ MALE CAP	I sterile
MC15	STARFIT™ MALE CAP (15/BOX)	I non-sterile
MC50	STARFIT™ MALE CAP (50/BOX)	I non-sterile
MFCAP	STARFIT™ MALE FEMALE CAP	I sterile
NGE-75	STARFIT™ NASOGASTRIC EXTENSION SET 75 cm	II a sterile
NGE-150	STARFIT™ NASOGASTRIC EXTENSIO SET 150 cm	II a sterile
UBA01	STARFIT™ UNIVERSAL BOTTLE ADAPTOR 14.5-27.5 mm	I sterile
BA-XS01	STARFIT™ BOTTLE ADAPTOR XS 15-16.5 mm	I sterile
BA-S01	STARFIT™ BOTTLE ADAPTOR S 18-19.5 mm	I sterile
BA-M01	STARFIT™ BOTTLE ADAPTOR M 18.5-20.5 mm	I sterile
BA-L01	STARFIT™ BOTTLE ADAPTOR L 20-21.5 mm	I sterile
BA-XL01	STARFIT™ BOTTLE ADAPTOR XL 25.5-27 mm	I sterile
SK01	STARFIT™ ENTERAL 3 WAYS STOPCOK	I sterile
MF01	STARFIT™ MEDICINE DOSE AID	I non-sterile
MFS01	STARFIT™ MEDICINE DOSE STRAW	I non-sterile
TR01	STARFIT™ MALE MALE TRANSFER CONNECTOR	I non-sterile
BR01	STARFIT™ ENTERAL CLEANING BRUSH	Non-sterile

Product Range and UDI-DI

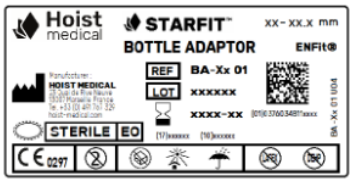
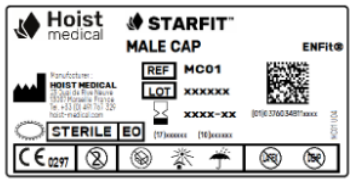
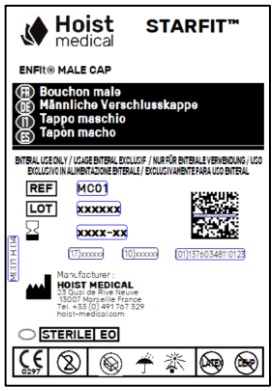
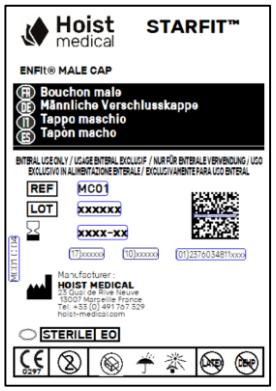
SKU	Basic UDI-DI	Unit UDI-DI	Box UDI-DI	Cardboard UDI-DI	Pallet UDI-DI
MC15	376034811400.07CE	03760348110102	13760348110109	23760348110106	33760348110103
SK01	376034811400.08CG	03760348111505	13760348111502	23760348111509	33760348111506
NS01	376034811400.04C8	03760348110560	13760348110567	23760348110564	33760348110561
NGE150	376034811400.01C2	03760348111437	13760348111434	23760348111431	33760348111438
BA-XL01	376034811400.06CC	03760348111420	13760348111427	23760348111424	33760348111421
BA-L01	376034811400.06CC	03760348111413	13760348111410	23760348111417	33760348111414
BA-M01	376034811400.06CC	03760348110188	13760348110185	23760348110182	33760348110189
BA-S01	376034811400.06CC	03760348110195	13760348110192	23760348110199	33760348110196
BA-XS01	376034811400.06CC	03760348110201	13760348110208	23760348110205	33760348110202
SS01	376034811400.03C6	03760348110157	13760348110154	23760348110151	33760348110158
MFCAP	376034811400.10C3	03760348110119	13760348110116	23760348110113	33760348110110

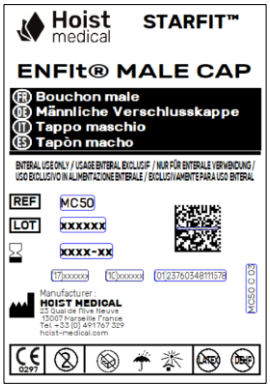
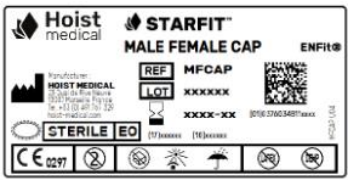
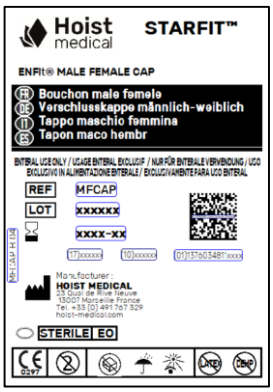
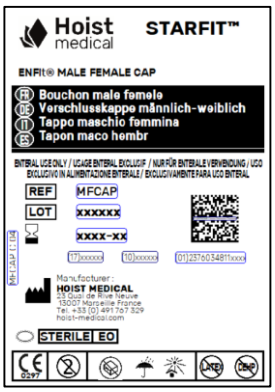
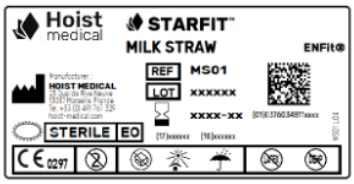
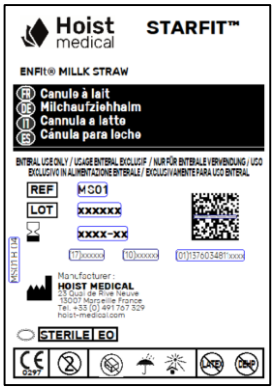
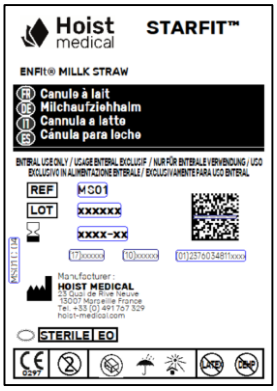
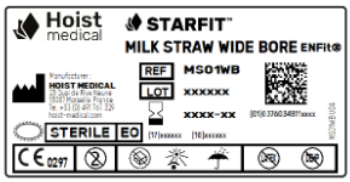
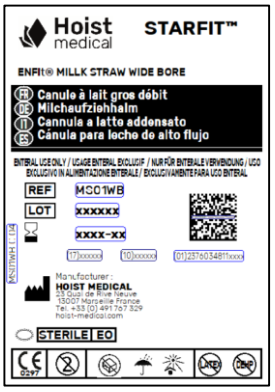
NGE75	376034811400.01C2	03760348110249	13760348110246	23760348110243	33760348110240
MS01	376034811400.02C4	03760348110171	13760348110178	23760348110175	33760348110172
UBA01	376034811400.06CC	03760348110218	13760348110215	23760348110212	33760348110219
MS01WB	376034811400.02C4	03760348110164	13760348110161	23760348110168	33760348110165
MC01	376034811400.07CE	03760348110126	13760348110123	23760348110120	33760348110127
MC50	376034811400.07CE	03760348111574	13760348111571	23760348111578	33760348111575
MF01	376043811400.12C9	03760348112465	13760348112462	23760348112469	33760348112466
MFS01	376043811400.13CB	03760348112472	13760348112479	23760348112476	33760348112473
TR01	376034811400.14CB	03760348112489	13760348112486	23760348112483	33760348112480
BR01	376034811400.15CD	03760348112496	13760348112493	23760348112490	33760348112497

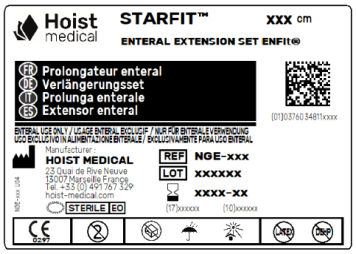
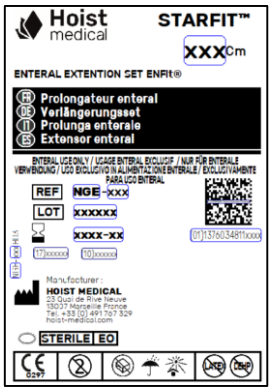
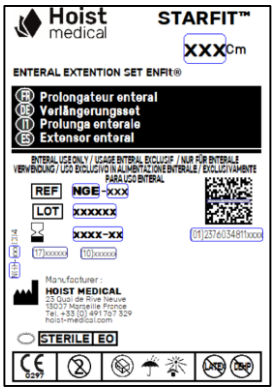
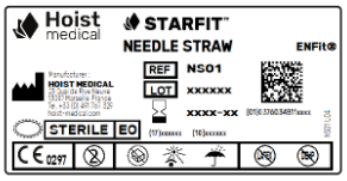
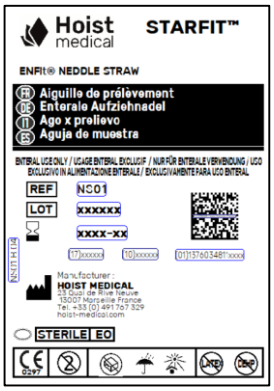
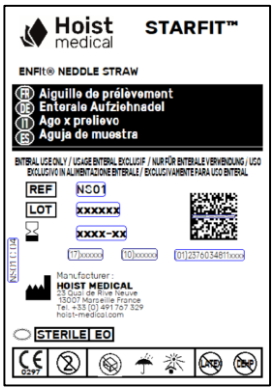
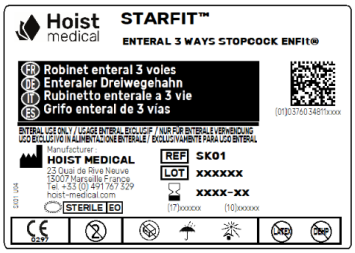
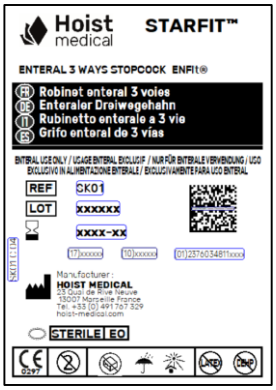
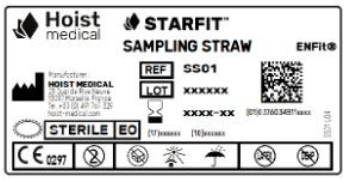
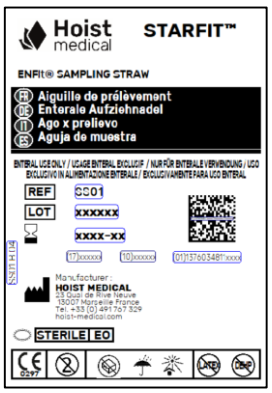
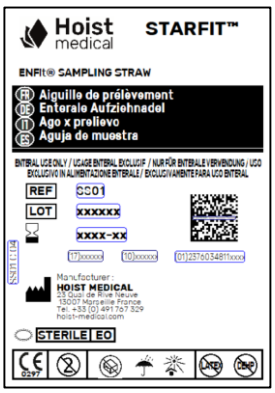
Presentation and packaging

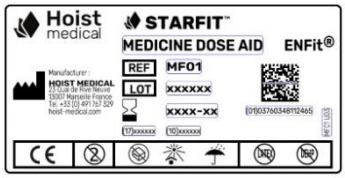
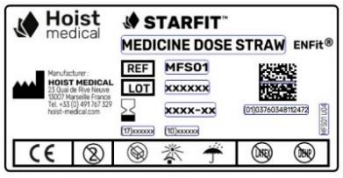
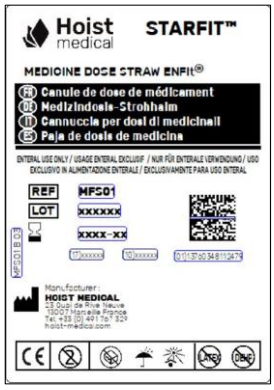
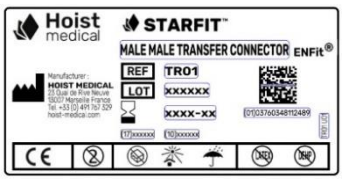
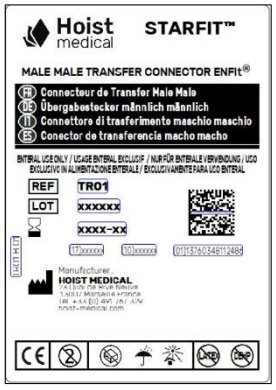
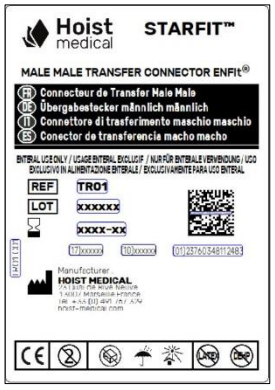
SKU	Individual Packaging	Quantity per Box	Quantity per Cardbord	Quantity par Pallet
MC15	Box of 15	600	9600	230400
SK01	Soft blister	25	400	9600
NS01	Soft blister	100	1600	38400
NGE150	Soft blister	25	400	9600
BA-XL01	Soft blister	100	1600	38400
BA-L01	Soft blister	100	1600	38400
BA-M01	Soft blister	100	1600	38400
BA-S01	Soft blister	100	1600	38400
BA-XS01	Soft blister	100	1600	38400
SS01	Soft blister	100	1600	38400
MFCAP	Soft blister	100	1600	38400
NGE75	Soft blister	40	640	15360
MS01	Soft blister	50	800	19200
UBA01	Soft blister	30	480	11520
MS01WB	Soft blister	50	800	19200
MC01	Soft blister	100	1600	38400
MC50	bag of 50	1000	16000	384000
MF01	Soft blister	50	800	19200
MFS01	Soft blister	100	1600	38400
TR01	Soft blister	100	1600	38400
BR01	bag of 10	100	1600	38400

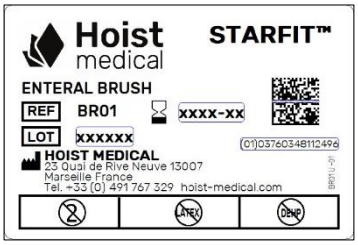
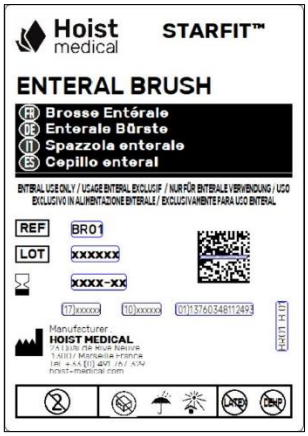
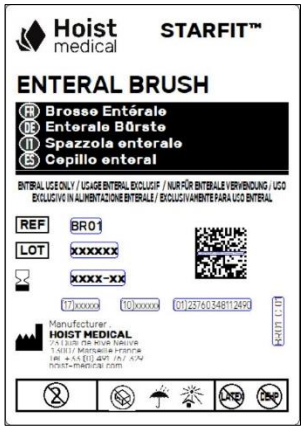
Labelling

Product	Unit Label	Box Label	Cardboard Label
Bottle Adaptor BA-xx01			
Male Cap MC01			
Male Cap x 15 MC15			

Male Cap x 50 MC50			
Male Female cap MFCAP			
Milk Straw MS01			
Milk straw wide bore MS01WB			

Enteral extension set NGE-XXX			
Needle Straw NS01			
3 Ways stopcock SK01			
Sampling straw SS01			

Universal bottle adaptor UBA01			
Medicine Dose Aid MF01			
Medicine Dose Straw MFS01			
Male Male Transfer Connector TR01			

Enteral Cleaning Brush BR01			

Composition

❖ Extension:

Component	Materials
Tube	PVC
Connectors	ABS

❖ Milk Straw:

Component	Materials
Tube	PVC
Connector	ABS

❖ Sampling Straw:

Component	Materials
Tube	PVC
Connector	ABS

❖ Sampling Needle:

Component	Materials
Connector	ABS
Needle	Stainless steel

❖ Universal Adaptor:

Component	Materials
Adaptor	PEBD
Connector	ABS

❖ Adaptor :

Component	Materials
Adaptor	PEBD

❖ 3-Way Enteral Stopcock:

Component	Materials
3-way Enteral stopcock	PC/PE
Connector	ABS

❖ CAP ENFit® :

Component	Materials
Connector	ABS

❖ Medicine Dose Aid:

Component	Materials
Connector	ABS
Nipple	ABS

❖ Medicine Dose Straw:

Component	Materials
Connector	ABS
Tube	PVC

❖ Male Male Transfer Connector:

Component	Materials
Connector	ABS

❖ Enteral Cleaning Brush:

Component	Materials
Brush	Plastic

- Absence of products of animal or biological origin
- Contains no drugs or products derived from human blood
- Contains no Latex, no DOP/DEHP, no Bisphenol A

Sterilization

- Sterilized by ethylene oxide
- The sterilization process is validated according to the standard EN ISO 11135 current version
- Ethylene oxide residues meets the requirements of the standards ISO 10993-7current version

Safety of use

- Single use
- Check the integrity of the packaging before use
- Store in a clean and dry place at room temperature
- 2 years expiry from the date of manufacturing

Regulatory

Applicable European Regulation	MDR (UE) 745/2017
DM Class	See classification table
Notified Body	DQS-CE0297
Certificate Registration number	551177 MDR2017Q
Certificate ID	100033594
First Market Launch in the EU	2024
Manufacturer	Hoist-Medical
Materio-vigilance Correspondent	Bernard Daurelle Phone: +33 607 386 354 e-mail: Bernard.daurelle@hoist-medical.com

Administrative Information

Address	Hoist-Medical 23 Quai de Rive Neuve 13007 Marseille France
Phone	+33 4 91767329
e-mail	commercial@hoist-medical.com
Web Site	hoist-medical.com