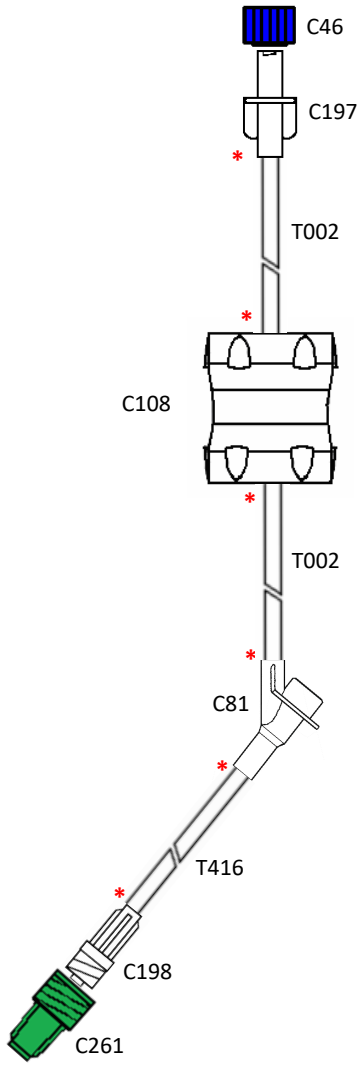
Quality Assurance		
PMH	**311.0734** **PRODUCT SPECIFICATION**	**PMH-04P-300TF-07**
Confidential	N.a.: n/a	
	Document Implementation Date: 01/02/2021	

Reference:	Description:	Technical draw nr:	Revision:
311.0734	EXTENSION LINE WITH FLOW REGULATOR , Y INJECCTION SITE, LUER LOCK FIXE AND PURGE FILTER, 10+10+20cm	0734	07

CO/N.a:	Bar Code	CDM	NPDM
CP008/15	EAN13: 5607716007344 EAN14: 25607716007348	n/a	n/a

Draw	Designation	Reference	Quantity	Raw material
	Blue cap	**C46**	1	PP COP PURELL RP 374R TRANSPARENTE + MB BLUE 4535
	Female luer	**C197**	1	PVC AMG102 W2152 CRY TRANSP.
	Tube 3.00x4.10mm, 10cm	**T002**	2	PVC (Plasticizer TOTM)
	Flow control	**C108**	1	ABS
	Y injection site	**C81**	1	ABS + SEBS
	Tube 2.50x4.10mm, 20cm	**T416**	1	PVC (Plasticizer TOTM)
	Male luer lock	**C198**	1	MABS TELUX 2812 HD
	Cap with purge filter	**C261**	1	HDPE 25055E + LDPE ALCUDIA PE 019 + Polytetrafluoroethylene

* = glue points

Sterile, non-pyrogenic fluid path in unopened undamaged package.

This product is made of non-latex components.

Product Specification made by: Quality Department	Product Specification Reviewed and Approved by: José Cordeiro
Made by: Position: Quality Director Date:	Reviewed and Approved by: Position: Technical Director Date:

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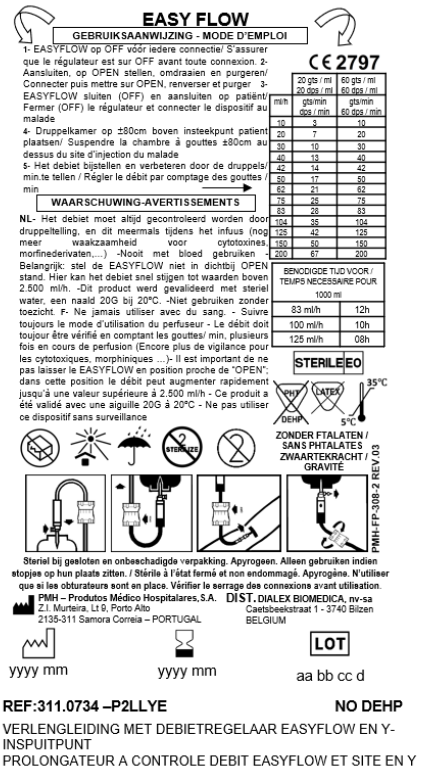
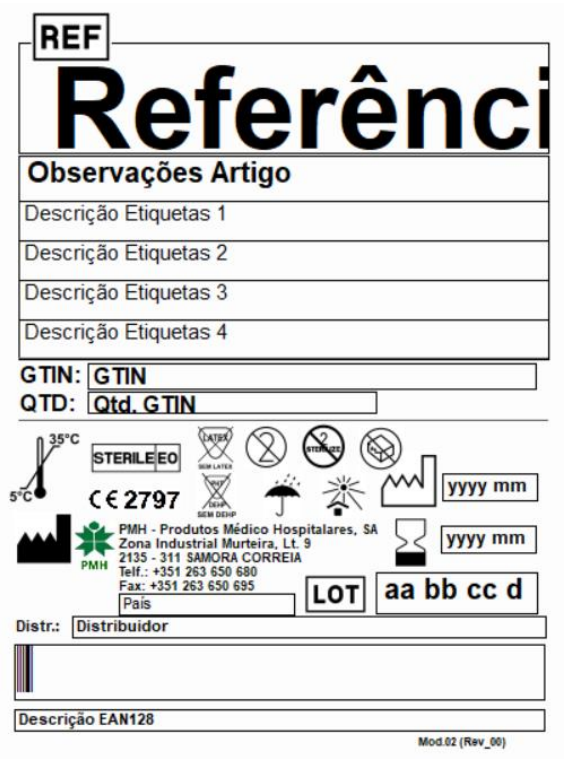
Packaging and Labelling / Photopolymers

Primary package **(1 unit per package)**				**Secondary package** **(50 units per bag x 2= 100 units per box)**			
Components	Reference	Dimension (cm)	Quantity	**Components**	Reference	Dimension (cm)	Quantity
Peelable bag	P04 + P17	W= 10 x H= 20	1	**Bag**	S13	W= 40 x H= 60	2
Photopolymer / Label	PMH-FP-308-2	n/a	1	**Box**	C174	L= 39 x W= 29,5 x H= 33,8	1
				Box Label	Mod_02	W= 11 x H= 14,8	1





PALLET

- 3 rounds of shrink wrap cover boxes, angles, pallet and the top of the last range of boxes
- 5 layers of 8 boxes. In staggered rows. Total Pallet maximum height = 180cm.

The batch number is aa bb cc d

aa: year number of production (ex 28 for 2020)
bb: year of production (ex 20 for 2020)
cc: month of production (ex 09 for September)
d: day of packaging (ex A for 1st working day of month)

Expiration is +60 months after batch number
Expiration date format is yyyy / mm
yyyy: year of expiration (example 2025)
mm: month of expiration (ex 09 for September)
For batch number 28 20 09 A -> Exp = 2025 / 09

Product information

Intended use	These devices are intended for channeling liquids for the purpose of infusion or administration into the body.
Mode of contact	These devices are: sterile; no-reusable; non-active and no-invasive
Duration of contact	The stablished duration of contact is short term.
Classification rules	Number 2
Risk class	Is
Sterilized by	Ethylene oxide
Shelf life	5 years
Biocompatibility	Product has been approved for use and has met the requirements for ISO 10993-1.
Production environment	Product is manufactured in an environmentally controlled room. Floor, surfaces and environment are monitored at defined frequencies to verify the controlled room conditions.
Labeling	Labels contain information for proper use including any warnings, contraindications, and symbology applicable. Labels are applied on the individual blister and on the outside of the cardboard box.
Traceability	PMH, SA guarantees full traceability of all the components used in the production of its devices.
Disposal	The user must dispose the device according to hospital disposal policy.
Storage	Store in a dry and clean place. Product should be retained in provided packaging until ready for use.
Warnings	Single-use only – Do not resterilize. Sterile, Non- Pyrogenic fluid pathway in unopened, undamaged package.
Production controls	• Each component is inspected during acceptance (visual inspections, dimensional checks and functional tests) to verify conformity with the requirements according to PMH, SA internal quality procedures. • During product production and release specific tests are performed according to PMH, SA internal quality procedures. • Once a month a Bioburden, Bacterial Endotoxins and Sterility tests are performed on samples taken from production to verify conformity of each process.
Quality system and Product certification	**Quality system is in compliance to:** ISO 13485:2016 **Product Certification:** The product is manufactured in compliance to Council Directive MDD 93/42/EEC as amended. **CE Certificate Number:** CE2797 **Notified Body:** BSI **MDD Device Classification:** Class Is
Legal manufacturer	PMH-Produtos Médico Hospitalares, SA Zona Industrial, da Murteira, Rua Guiné Bissau, Lt. 9, 2135-327 Samora Correia
Assembly site	• PMH-Produtos Médico Hospitalares, SA Zona Industrial, da Murteira, Rua Guiné Bissau, Lt. 9, 2135-327 Samora Correia • PMH-Produtos Médico Hospitalares, SA, Zona Industrial Nº1 – Guilhufe, 4560-164 Penafiel