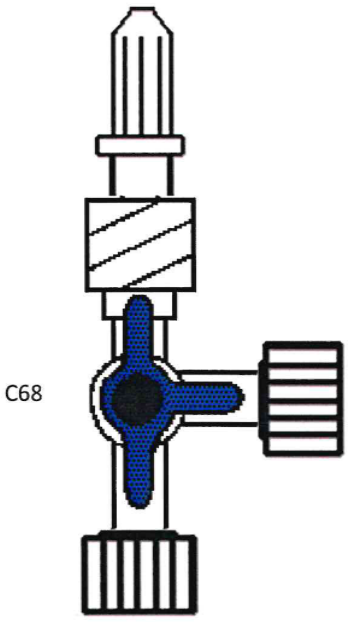
Quality Assurance			
PMH	**AMT0031** **PRODUCT SPECIFICATION**		**PMH-04P-300TF-07**
Confidential	N.a.: CP047/21	Rev: 01	
	Document Implementation Date: 29/11/2021		

Reference:	Revision:	CO/N.a:	Bar Code	CDM	NPDM
AMT0031	00	n/a	EAN13: 5607716100311 EAN14: 25607716100315	n/a	n/a

Description:

3-WEGE-HAHN BLAU LIPID RESISTENT

Draw	Designation	Reference	Quantity	Raw material
C68 	Blue stopcock ¾ way	**C68**	1	MAKROLON RX 1805 451118 + HDPE HD6706.17 + KAFRIT CC 62650 LL BLUE + POLYPROPYLENE 13R9A + 360 MEDICAL FLUID 12500cSt + 360 MEDICAL FLUID 1000cSt

Technical draw:	Nr:	Revision:	CO/N.a:
	0031	00	n/a

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: Vania Reis Position: Quality Assistant Date: 13/12/2022	Reviewed and Approved by: Position: Technical Director Date: 13/12/2022

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