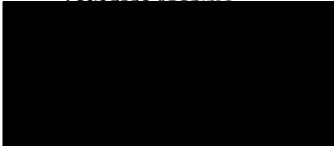




P M H
P R O D U T O S
M E D I C O
H O S P I T A L A R E S

Sanidade Assis...



Safety Information

Dear Customer, Care Services, Risk Management, Materiovigilance, Pharmacy

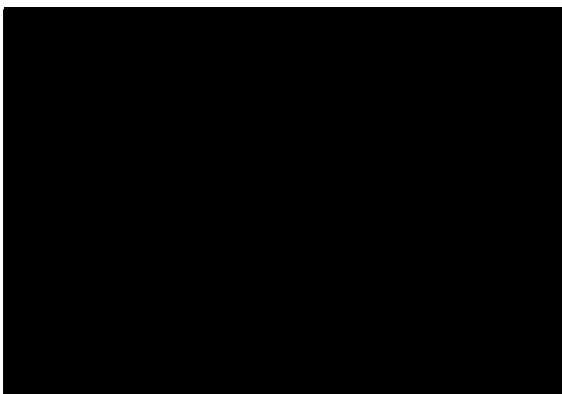
In agreement with the distributor AMT Medica GmbH, PMH SA issue this safety information about the medical device with the reference AMT 0111 "Infusion filter of 0,2 μm ".

PRODUCT INFORMATION

REFERENCE:	AMT0111
BATCH:	All batches
DESCRIPTION	Infusion Filter of 0,2 μm

PROCESS INFORMATION

HEALTHCARE FACILITY WHERE INCIDENT OCCURRED	UKSH Campus Kiel
PMH INTERNAL NUMBER	012-2020
BFARM CASE NUMBER	12731/20



**PROBLEM
DESCRIPTION**

IT WAS OBSERVED A LEAKAGE ON THE DEVICE NEAR THE LUER LOCK CONNECTION

**RISK FOR
HEALTH**

There is no risk for patient and user's health due to the use of this device.
The problem is not associated with the use of the product, but due intensive use of alcoholic solutions during the disinfection process.

The medical device with the reference AMT0111 does not present any risk for the health of the patients and users.

After PMH internal investigation conclude when it is used excess of alcoholic disinfectant solutions could promote a tension in the raw material of the filter box (near the connector) that could lead the presence of leakage.

As corrective Preventive action PMH add in the label a Caution "This device is not suitable for isopropyl alcohol-based solutions"

**SAFETY
INFORMATION**

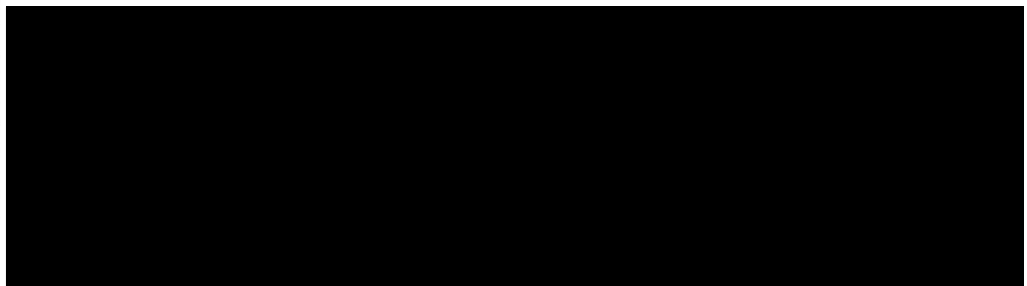
a) **Please if you are using AMT0111 infusion filter** be aware that this product, related to all batches, is sensitive to disinfectant isopropyl alcohol-based solutions.

b) **Please verify** if there are other batch of the same product, without this information in the label, and be aware that this product is sensitive to disinfectant isopropyl alcohol-based solutions

c) A new label information will be introduced in the new customer orders

For any question or clarification of this Safety Information, please feel free to contact:

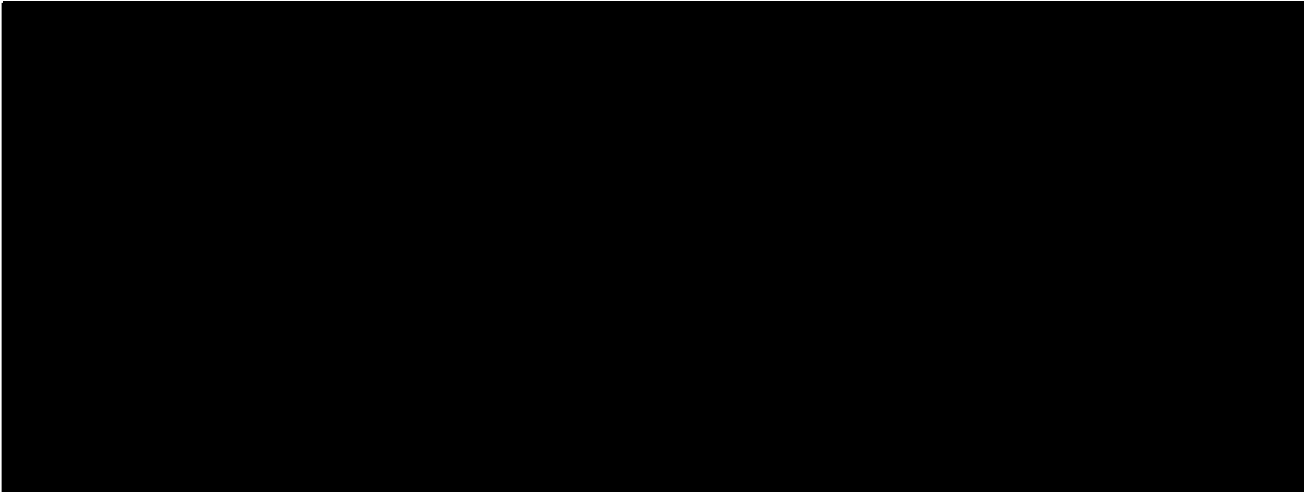
CONTACT:



Please transmit this notice to all that need to be aware within your organization or any other entity that could be directly or indirectly affect by this event.

The quality of our products and services is the main concern of PMH, SA. We sincerely apologize you for all the inconvenience caused. Please feel free to contact PMH or AMT in case of doubts for the contact above mentioned.

Sincerely yours,



Annex I

Below it is possible to verify the caution information in the new label:



D – Auf Sterilität und Pyrogenfreiheit geprüft.
Produkt nicht verwenden, wenn die
Schutzkappen gelockert oder abgefallen sind,
oder die Verpackung beschädigt ist.
Überprüfen Sie alle Anschlüsse vor dem
Gebrauch.



Achtung - Dieses Produkt ist nicht für
Lösungen auf Isopropylalkoholbasis geeignet



LATEX FREI



DEHP FREI



CE 2797



35°C
5°C

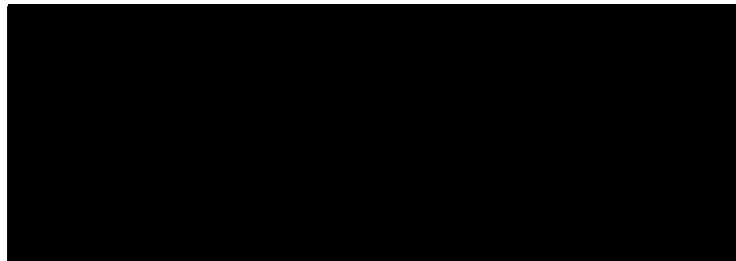


STERILE EO

PMH-FP-300-21 REV.00



PMH - PRODUTOS MÉDICO HOSPITALARES, S.A
Z. I. MURTEIRA Lt. 9 2135 SAMORA CORREIA - PT
Tel. + 351 263 650 680 FAX. + 351 263 650 695



Annex II

To be completed and return

PRODUCT INFORMATION

REFERENCE:	AMT0111
BATCH:	All batches
DESCRIPTION	Infusion Filter of 0,2µm

PROCESS INFORMATION

HEALTHCARE FACILITY WHERE INCIDENT OCCURRED	UKSH Campus Kiel
PMH INTERNAL NUMBER	012-2020
BFARM CASE NUMBER	12731/20

A)

Hospital Name	
Address:	
Phone Number	
Name	
Job Title	
Signature	
Date	

B)

I have read and understood the content of this action.

C)

Please return the document to:

