

Urgent!
Field Safety Notice (FSN)
-Annex II-
List of affected products



This Annex II is considered as a supplementary attachment to the Field Safety Notice of FSCA-2018-10-01

FSCA Number: FSCA-2018-10-01

FSCA Title: Potential leakage at QUADROX-i Neonatal blood inlet connector

Affected Product: All variants and sets of QUADROX-i Neonatal which include the reducing screw adapter 1/4" x 3/16" (Ref. No. 70104.8593) (see list below)

Affected Timeframe: The shelf life for oxygenators is defined for two years, therefore the considered timeframe is:
Products manufactured between October 2016 – October 2018, with an expiration date of October 2018 and October 2020.

Material No.	Material Description
701046979	HMO 10000#QUADROX-i neo.o.Filt.micro. So
701047003	HMO 11000#QUADROX-i neo.m.Filt.micro. So
701049279	VKMO 11000#QUADROX-i Neo. mit Reservoir
701050109	VKMO 10000#QUADROX-i Neo. mit Reservoir
701053421	HQ 89709-1#Neonate Pack w.VKMO 11000
701053444	BO-VKMO 11000#QUADROX-i Neo.+BO Reserv.
701053453	BE-VKMO 11000#QUADROX-i Neo.+BE Reserv.
701054131	BO-HQV 90500#5 - 10 kg 1/4-1/4+QUADROX-I
701054133	BO-HQV 90501#0 - 5 kg 3/16-1/4+QUADROX-I
701054973	BO-HQV 48412#Custom HMO 11000 + BO-VHK 3
701055120	VKMO 10000-USA#QUADROX-i Neo.+ Reservoir
701055207	VKMO 11000-USA#QUADROX-i Neo.+Reservoir
701062982	HQ 89709#Neonate Pack w.VKMO 10000

Urgent!
Field Safety Notice (FSN)
-Annex II-
List of affected products



701063689	HMO 10000-J#QUADROX-i neo.o.Filt.micr.So
701063696	HMO 11000-J#QUADROX-i neo.m.Filt.micr.So
701063846	BO-VKMO 10000-J#QUADROX-i Neo.+BO Reser.
701063847	BO-VKMO 11000-J#QUADROX-i Neo.+BO Reser.
701068357	HQV 0776#Kinder Set 11000, Mod.Tübingen
701070187	BO-HQV 111600#N-B/Lilliput Set
701071777	HQV 86303#Neonatal Pack

Please note: SSUs are called to actively find out whether the listed devices have been forwarded or sold into any other country. That country where the unit is currently located is also an affected country. Please send any information about forwarding and selling to other countries to:

FSCA.cp@getinge.com.

We apologize for any inconvenience this may cause you and we will do our utmost to carry through this action as swiftly as possible.

For follow up actions, please contact us on FSCA.cp@getinge.com.

Sincerely,

Maquet Cardiopulmonary GmbH
Kehler Str. 31
76437 Rastatt
GERMANY