

URGENT FIELD SAFETY NOTICE

Description: Sterile TULIPS Nipple Shields
Part No.: 63.00.284
63.00.285
FSCA Identifier: 2019-010
Type of action: Device Destruction

Unterägeri, 2019-02-15

Attention:

Distributors & Customer of Ardo medical AG that received affected product lots of sterile TULIPS nipple shields.

Details of affected devices:

Affected are all sterile TULIPS nipple shields

- 63.00.284 TULIPS Nipple shields size M sterile (200 pcs)
- 63.00.285 TULIPS Nipple shields size L sterile (200 pcs)

with lot number smaller than 190086.

Description of the problem:

During a transport simulation according to ASTM D4169, the packaging of the product was found defective. Therefore, the sterility of the product cannot be guaranteed after transportation to our customers.

Advise on action to be taken by the user:

Because the sterility of the products cannot be guaranteed, all affected production lots (lot number smaller than 190086) must be discarded.

Please send discard record together with the quantity and lot number of the discarded products to the according sales representative until 2019-03-31 in order to get credit notes for the discarded parts.

Transmission of this Field Safety Notice:

This Field Safety Notice must be sent to all customers that received

- 63.00.284 TULIPS Nipple shields size M sterile (200 pcs)
- 63.00.285 TULIPS Nipple shields size L sterile (200 pcs)

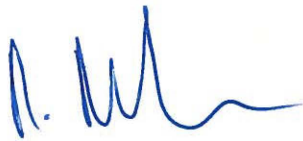
with lot numbers smaller than 190086.

Contact reference person:

Ardo medical AG
Roger Dubach
Director QM & RA
Gewerbstrasse 19
6314 Unterägeri
Switzerland

Mail: gmb@ardo.ch
Telephone: +41 41 754 70 62
Fax: +41 41 754 70 71

The undersign confirms that this notice has been notified the appropriate Regulatory Agency



Roger Dubach
Director QM & RA



Philipp Schilliger
COO