

REGISTERED (R)

Basel, January 24, 2017

Medical device recall:

KORING® Stoma support Ring KR-XX: Suspension of the CE-certificate EU1306403 by the notified body Nemko AS NB 0470

Measure:

Customer notification of the CE-suspension EU1306403 and recall

Product Codes:

KORING® KR-25, KR-30, KR-35

Addressed to:

Medical specialists and distributors

Ladies and gentlemen,

This letter is to inform you about the CE suspension of the KORING[®] Stoma Support Ring.

Corrective measure:

Immediate recall of KORING[®] Stoma support Ring KR-XX

GTIN-13	LOT	PRODUCT NAME	ARTICLE N ^o .
7640167520015	KR14258 / KR13191	KORING [®]	ØKR-25mm inner diameter
7640167520022	KR14473	KORING [®]	ØKR-30mm inner diameter
7640167520008	KR14258 / KR13192	KORING [®]	ØKR-35mm inner diameter

Underlying cause for the CE suspension

1. Because of a regulatory non-conformity, the product KORING[®] Stoma Support Ring is no longer allowed to be sold or implanted in Switzerland and the European Union. Until now, there is no incident reported in connection with the safety of the patients, the integrity of the product, the packaging, or the sterility of the product.
2. For the implanted KORING[®] Stoma Support Ring, from a medical point of view, no special measures must be taken.

Corrective measure:

As European representative of the medical device KORING[®], we are obliged to kindly ask all customers who have this medical device in stock to send it back immediately to:

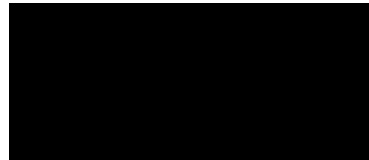
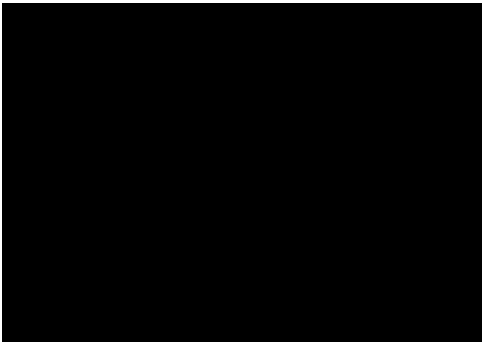
Koring AG
Hochbergerstrasse 60C
CH - 4057 Basel

Based on the Federal Law HMG Art. 59, MepV 812.213 section 5. Art. 14⁶³ – 15^{a65}, Council Directive 93/42/EEC, the post-market-surveillance, market surveillance & vigilance for the implanted KORING[®] Stoma support Ring is assured by the company.

Please return to us all KORING[®] product(s) from your stock.
Complete the attached form and include it with the returned product(s).

If you have questions, please do not hesitate to contact us. Thank you very much for your cooperation and understanding.

Yours sincerely,



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Recall Document

Hospital / Company

Department

Address

ZIP code City

Contact Person:

Telephone:

E-Mail :

Date:

RETURNED GOODS

Art. No. KR-XX	SN	LOT	Visum	please leave blank
KR-35	K1000...	KR.....		
KR-35	K1000...	KR.....		
KR-30	K1000...	KR.....		
KR-30	K1000...	KR.....		
KR-25	K1000...	KR.....		
KR-25	K1000...	KR.....		

24.01.2017

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