S.Possidonio, March 25th 2016

To :
MERMAID MEDICAL A/S
FRYDENSBERGVEJ 25
Zip Code DK-3660 – STENLOESE - DENMARK

Subject : FSN

Product Code	Lot	Description
PS15050-10	02134-15 02173-15 00412-16	Bone marrow aspiration needle mod. PERFECTUS 15G x 50 MM

Dear Valued Customer,

Company MEDAX – manufacturer of the medical device PERFECTUS PS15050-10 – is initiating a voluntary recall of the product indicated in the above table.

Our records show that your facility has purchased one or more of the affected lots.

Important note:

This notice must be transmitted to any structure where the potentially affected devices may have been transferred.

Problem description:

The cannula may be not properly assembled with the handle of the needle.

Potential risk:

There is a possibility that by extracting the needle after the procedure, the cannula could become detached from the handle.

Medax Srl Unipersonale
Headquarters: Via S. Pertini, 4 • 41039 • San Possidonio (MO) • Italy
Company direct No. : +39 0535 1812757 • Fax No : +39 0535 1812744
email: customercare@medax.it • PEC: medax@legalmail.it • www.medax.it

Registered Office: Via R. Piva, 1/A • 46025 • Poggio Rusco (MN) • Italy
Vat N. /Fiscal Code N. Iscriz. Reg. Impr.: MN 02669860369 • N. REA: MN 233527, MO 403036 • Capitale Sociale Euro 100.011,00 i.v.

Required Actions by Distributors and Users

- Please identify and quarantine any devices of the affected lots in your inventory.
- Provide a copy of this FSN and FSCA response from to all customers who may have received affected devices
- Ask these customers to complete the FSCA response form and return to you
- Confirm to Medax that you have completed the required activity for all of your impacted customers.

Upon receipt of the completed FSCA response form, MEDAX will contact you to arrange for the return of the affected devices and the provision of replacement devices.

We inform you that the competent authorities were advised on this Field Safety Notice.

Medax places utmost importance to product quality and safety of our patients.
We appreciate your attention to this matter and apologize for any inconvenience this issue may have caused. If you have any question or concerns regarding this recall, please contact your MEDAX customer service team by email at:
sales@medax.it
qa@medax.it
customercare@medax.it

We thank you for your attention and cooperation

Best Regards

Faithfully Legal Representative

Nicola Camellini Moretti

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ANNEX 1

Filed Safety Corrective Action (FSCA) Response Form

Ref. No.: FSCA/2016/001

Date: March 25th 2016

Please precise the collection address:
Organization/Company :
Service and Head:
Address:
City:
Phone:
Email:
Fax:

- ❑ We do not have any of the affected devices below listed
- ❑ We have the following affected devices:

Product Code	Lot	Quantity
PS15050-10	02134-15	
PS15050-10	02173-15	
PS15050-10	00412-16	

Upon receipt of this form, a MEDAX representative will contact you to arrange the return and replacement of affected devices.

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