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Urgent Summarized Field Safety Notice/Zusammengefasster Sicherheitshinweis vor Ort

Dear customer,

As manufacturers of the **BIOPSY NEEDLES** listed in this document, we hereby notify you of the issue of a Field Safety Corrective Action relating to the products described (Annex 1 – List of the Impacted batches in German Market).

Sehr geehrter Kunde,

*Als Hersteller der in diesem Dokument aufgeführten **BIOPSY-NADELN** informieren wir Sie hiermit über das Problem einer Korrekturmaßnahme für die Feldsicherheit in Bezug auf die beschriebenen Produkte (Anhang 1 - Liste der betroffenen Chargen auf dem deutschen Markt).*

Explanation of the problem

GTA S.r.l. is a manufacturer of class IIa and IIb medical devices.

The devices are marketed in sterile form, after having undergone an ethylene oxide sterilization process performed by the company Steril Milano Srl.

We have received communication from the sterilizer about the falsification of the process parameters of the sterilization cycles.

So, we conducted a thorough investigation accompanied by sterility tests and residue eto, with positive feedback on all the involved products.

As a precaution, we decide to recall the devices (listed in Annex 1) in stock at our distributors.

With regard to hospitals and health services, the immediate quarantine and segregation of the same devices listed in Annex 1 present in the structure is required.

In Annex no. 1 you can find the list of the affected lots.

Erklärung des Problems

GTA S.r.l. ist Hersteller von Medizinprodukten der Klassen IIa und IIb.

Die Geräte werden in steriler Form vermarktet, nachdem sie einem Ethylenoxid-Sterilisationsverfahren unterzogen wurden, das von der Firma Steril Milano Srl durchgeführt wurde.

Wir haben vom Sterilisator eine Mitteilung über die Fälschung der Prozessparameter der Sterilisationszyklen erhalten.

Daher führten wir eine gründliche Untersuchung durch, die von Sterilitätstests und Rückstands-Eto begleitet wurde, mit positivem Feedback zu allen beteiligten Produkten.

Als Vorsichtsmaßnahme beschließen wir, die in Anhang 1 aufgeführten Geräte bei unseren Händlern zurückzurufen. In Bezug auf Krankenhäuser und Gesundheitsdienste ist die sofortige Quarantäne und Trennung derselben Geräte erforderlich, die in Anhang 1 der Struktur aufgeführt sind.

In Anhang Nr. 1 finden Sie die Liste der betroffenen Lose.

Clinical impact

The use of non-sterile devices may lead to an increased risk of patient infection.

We would like to specify that GTA Srl has never been notified of adverse events or damage to patients potentially attributable to the problem covered by this report.

There are no specific follow-up actions for patients, where the product has already been used.

Klinische Auswirkungen

Die Verwendung nicht steriler Geräte kann zu einem erhöhten Infektionsrisiko für den Patienten führen.

Wir möchten darauf hinweisen, dass GTA Srl niemals über unerwünschte Ereignisse oder Schäden an Patienten informiert wurde, die möglicherweise auf das in diesem Bericht behandelte Problem zurückzuführen sind.

Es gibt keine spezifischen Folgemaßnahmen für Patienten, bei denen das Produkt bereits verwendet wurde.

All batches of potentially non-sterile devices supplied to your company are listed in Annex 1 "List of Impacted batches"

Actions required to distributors and economic operators

1. Immediately suspend deliveries, identify and quarantine all the items in your possession which are listed in Annex no. 1 "List of Impacted batches".
2. Share this Field Safety Notice within your organization with all interested parties. If you have distributed the products covered by this FSN to third parties, identify these subjects and forward this letter to them immediately, communicating to each hospital the detailed list of the goods subject to this action that have been supplied by you, using the template of the Annex no. 2 "Letter of the Distributor to Hospitals" – Table A1 (making sure to fill in Table A1 with the detail of the article codes and the lots destined for that hospital).
3. Fill in and sign the attached Annex no. 3 "Acknowledgment of the distributor" specifying the quantity of the quarantined goods, including their lot number, their code and inform GTA Srl by sending an email to qa@gta-medical.com and info@gta-medical.com as soon as possible / within 10 days of receipt of this letter.
4. GTA Srl will contact you to organize the collection of the goods. GTA Srl will replace the goods as soon as possible.

Actions required of hospitals and health facilities

1. Immediately discontinue use, identify and quarantine all items listed in Table A1, that are still present at your facility, that are new, unused, and still in their original packaging.
2. Fill in and sign the attached Annex no. 4 "Acknowledgement of hospitals and health facilities" specifying the quantity of the goods placed in quarantine, including their lot number, their code and inform your dealer and GTA Srl by sending an email to qa@gta-medical.com and info@gta-medical.com as soon as possible and in any case within 10 days of receipt of this letter.
3. Wait for information from the distributor and GTA Srl for the handling of the involved goods.

**Corrective Actions in place**

GTA Srl is completing the qualification of a new supplier for the sterilization process.

Contacts

For further information regarding this FSN please contact GTA Srl at +39.347.2441014 or by email at the address qa@gta-medical.com or info@gta-medical.com and your distributor.

We confirm that the relevant competent authorities have been notified of the actions described herein. We would like to mean that the safety of our devices is a primary objective for us, in issuing this FSN GTA we wanted to maintain a prudent and collaborative approach, we trust to manage the planned actions in the best possible way.

We apologize for any inconvenience this situation may cause. We are available for any clarification.

Annex1-List of Impacted batches Medical technologies

Name	Description	Code	Lot #	Company
NAXI	Biopsy Needles	NAXI 1603	LP0001/18	Medical Tech.
BOHR	Biopsy Needles	MN 0915	LP0036/18	Medical Tech.
BOHR	Biopsy Needles	MN 1110	LP0034/18	Medical Tech.
SLB	Biopsy Needles	GTZ 1616	LP0010/18	Medical Tech.
SLB	Biopsy Needles	GTZ 1410	LP0061/18	Medical Tech.
SLB	Biopsy Needles	GTZ 1620	LP0065/18	Medical Tech.
BOHR	Biopsy Needles	MN 0910	LP0058/18	Medical Tech.
NAXI	Biopsy Needles	NAXI 1801	LP0114/18	Medical Tech.
NAXI	Biopsy Needles	NAXI 1801	LP0112/18	Medical Tech.
SLB	Biopsy Needles	GTZ 1820	LP0030/18	Medical Tech.
SLB	Biopsy Needles	GTZ 1810	LP0019/18	Medical Tech.
SLB	Biopsy Needles	GTZ 1620	LP0105/18	Medical Tech.
SLB	Biopsy Needles	GTZ 1620	LP0106/18	Medical Tech.
SLB	Biopsy Needles	GTZ 1616	LP0204/18	Medical Tech.
NAXI	Biopsy Needles	NAXI 1501	LP0206/18	Medical Tech.
NAXI	Biopsy Needles	NAXI 1501	LP0191/18	Medical Tech.
NAXI	Biopsy Needles	NAXI 1501	LP0213/18	Medical Tech.
NAXI	Biopsy Needles	NAXI 1501	LP0415/18	Medical Tech.
BOHR	Biopsy Needles	MN 1110	LP0458/18	Medical Tech.
CAV	Biopsy Needles	CAV 1810	LP0387/18	Medical Tech.
SLB	Biopsy Needles	GTZ 1816	LP0498/18	Medical Tech.
NAXI	Biopsy Needles	NAXI 1501	LP0499/18	Medical Tech.
CAV	Biopsy Needles	CAV 1816	LP0495/18	Medical Tech.
CAV	Biopsy Needles	CAV 1610	LP0505/18	Medical Tech.
CAV	Biopsy Needles	CAV 1820	LP0503/18	Medical Tech.
NAXI	Biopsy Needles	NAXI 1501	LP0499/18	Medical Tech.
NAXI	Biopsy Needles	NAXI 1501	LP0527/18	Medical Tech.
NAXI	Biopsy Needles	NAXI 1501	LP0005/19	Medical Tech.
NAXI	Biopsy Needles	NAXI 1603	LP0064/18	Medical Tech.
NAXI	Biopsy Needles	NAXI 1603	LP0402/18	Medical Tech.
NAXI	Biopsy Needles	NAXI 1603	LP0061/19	Medical Tech.
CAV	Biopsy Needles	CAV 2016	LP0029/19	Medical Tech.
SLB	Biopsy Needles	GTZ 1616	LP0460/18	Medical Tech.
NAXI	Biopsy Needles	NAXI 1601	LP0062/19	Medical Tech.
BOHR	Biopsy Needles	MN 0910	LP0063/19	Medical Tech.
BOHR	Biopsy Needles	MN 1110	LP0149/19	Medical Tech.
SLB	Biopsy Needles	GTZ 2010	LP0362/18	Medical Tech.
SLB	Biopsy Needles	GTZ 1816	LP0109/19	Medical Tech.
NAXI	Biopsy Needles	NAXI 1803	LP0271/18	Medical Tech.
SLB	Biopsy Needles	GTZ 1816	LP0208/19	Medical Tech.
SLB	Biopsy Needles	GTZ 2010	LP0209/19	Medical Tech.
BOHR	Biopsy Needles	MN 0910	LP0207/19	Medical Tech.
NAXI	Biopsy Needles	NAXI 1501	LP0204/19	Medical Tech.
BOHR	Biopsy Needles	MN 1110	LP0365/19	Medical Tech.
SLB	Biopsy Needles	GTZ 1616	LP0353/19	Medical Tech.

Name	Description	Code	Lot #	Company
SLB	Biopsy Needles	GTZ 2016	LP0354/19	Medical Tech.
SLB	Biopsy Needles	GTZ 1610	LP0112/19	Medical Tech.
BOHR	Biopsy Needles	MN 0910	LP0267/19	Medical Tech.
SLB	Biopsy Needles	GTZ 1420	LP0352/19	Medical Tech.
NAXI	Biopsy Needles	NAXI 1601	LP0062/19	Medical Tech.
NAXI	Biopsy Needles	NAXI 1501	LP0343/19	Medical Tech.
BOHR	Biopsy Needles	MN 0910	LP0381/19	Medical Tech.
BOHR	Biopsy Needles	MN 1110	LP0383/19	Medical Tech.
BOHR	Biopsy Needles	MN 0715	LP0389/19	Medical Tech.
CAV	Biopsy Needles	CAV 1816	LP0402/19	Medical Tech.
NAXI	Biopsy Needles	NAXI 1501	LP0343/19	Medical Tech.
CAV	Biopsy Needles	CAV 1610	LP0359/19	Medical Tech.
SLB	Biopsy Needles	GTZ 1410	LP0407/19	Medical Tech.
SLB	Biopsy Needles	GTZ 1610	LP0398/19	Medical Tech.
SLB	Biopsy Needles	GTZ 1816	LP0446/19	Medical Tech.
SLB	Biopsy Needles	GTZ 1616	LP0409/19	Medical Tech.
CAV	Biopsy Needles	CAV 2016	LP0487/19	Medical Tech.
SLB	Biopsy Needles	GTZ 1610	LP0486/19	Medical Tech.
SLB	Biopsy Needles	GTZ 1616	LP0485/19	Medical Tech.
CAV	Biopsy Needles	CAV 1610	LP0504/19	Medical Tech.
SLB	Biopsy Needles	GTZ 2016	LP0505/19	Medical Tech.
NAXI	Biopsy Needles	NAXI 1501	LP0517/19	Medical Tech.
NAXI	Biopsy Needles	NAXI 1603	LP0499/19	Medical Tech.
NAXI	Biopsy Needles	NAXI 1603	GT0026/20	Medical Tech.
SLB	Biopsy Needles	GTZ 1420	GT0020/20	Medical Tech.
SLB	Biopsy Needles	GTZ 1416	LP0506/18	Medical Tech.
SLB	Biopsy Needles	GTZ 2010	GT0075/20	Medical Tech.
BOHR	Biopsy Needles	MN 0910	LP0467/19	Medical Tech.
NAXI	Biopsy Needles	NAXI 1501	LP0518/19	Medical Tech.
SLB	Biopsy Needles	GTZ 1416	LP0432/19	Medical Tech.
BOHR	Biopsy Needles	MN 0910	GT0037/20	Medical Tech.
NAXI	Biopsy Needles	NAXI 1601	GT0085/20	Medical Tech.
SLB	Biopsy Needles	GTZ 1816	LP0446/19	Medical Tech.
NAXI	Biopsy Needles	NAXI 1503	GT0025/20	Medical Tech.
CAV	Biopsy Needles	CAV 1816	GT0078/20	Medical Tech.
SLB	Biopsy Needles	GTZ 1616	LP0485/19	Medical Tech.
SLB	Biopsy Needles	GTZ 1610	GT0099/20	Medical Tech.
CAV	Biopsy Needles	CAV 1816	GT0101/20	Medical Tech.
SLB	Biopsy Needles	GTZ 1616	GT0100/20	Medical Tech.
SLB	Biopsy Needles	GTZ 1616	GT0327/20	Medical Tech.
SLB	Biopsy Needles	GTZ 1616	GT0327/20	Medical Tech.
SLB	Biopsy Needles	GTZ 1616	GT0133/20	Medical Tech.
SLB	Biopsy Needles	GTZ 1410	LP0515/18	Medical Tech.
SLB	Biopsy Needles	GTZ 1420	GT0324/20	Medical Tech.
SLB	Biopsy Needles	GTZ 1816	GT0323/20	Medical Tech.

Name	Description	Code	Lot #	Company
NAXI	Biopsy Needles	NAXI 1501	GT0322/20	Medical Tech.
NAXI	Biopsy Needles	NAXI 1603	GT0328/20	Medical Tech.
BOHR	Biopsy Needles	MN 1110	GT0319/20	Medical Tech.
BOHR	Biopsy Needles	MN 1110	GT0258/20	Medical Tech.
NAXI	Biopsy Needles	NAXI 1501	GT0460/20	Medical Tech.
NAXI	Biopsy Needles	NAXI 1501	GT0322/20	Medical Tech.
NAXI	Biopsy Needles	NAXI 1501	LP0518/19	Medical Tech.
BOHR	Biopsy Needles	MN 0910	GT0410/20	Medical Tech.
BOHR	Biopsy Needles	MN 1115	GT0491/20	Medical Tech.