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Recall concerning Metrax, GE, Schiller and GS Defibrillation Electrodes

Dear Customer and User of our Defibrillation Electrode for Children

SCHILLER Médical SAS (FR)	0-21-0000 (DF66 / 50352)
SCHILLER Médical SAS (FR)	0-21-0021 (DF66C / 50353)
SCHILLER Médical SAS (FR)	W1404262 (DF67 / 50354)
Schiller AG (CH)	2.155062 (DF70 / 50463)
Schiller AG (CH)	2.155064 (DF70 / 50609)
GS	04325.2 (DF61 / 50125)
GS	05120.2 (DF68 / 50531)
Metrax	73672 (DF38 / 50395)
Metrax	18841 (DF63 / 50648)
GE	2059144-005 (DF69 / 50461)

During an internal investigation triggered by market feedback, it was discovered that during the use of these defibrillation electrodes a possibility for arcing and a resulting malfunction exists. This malfunction can occur with defibrillation electrodes that are older than 2 years.

This could lead to a situation, in which a patient who is in a life threatening situation requiring a defibrillation can receive such therapy only with a delay or not at all. The precise cause for this is still under investigation.

The internal investigation has revealed that this potential malfunction can occur with these electrodes after duration of storage of about 2 years or more. All affected lot numbers of these types with a storage time over 18 months have been recalled in the recall of November 2014. All lot numbers that are currently on the market and are labeled with an expiration date of more than 2 years are called proactively in this recall from the market.

Bank: UniCredit Bank Austria AG
EUR: IBAN: AT52 1100 0008 9401 2400 BIC: BKAUATWW
USD: IBAN: AT10 1200 0008 9401 2424 BIC: BKAUATWW
Erfüllungsort und Gerichtsstand für Lieferung und Zahlung ist Innsbruck.
Der Verkauf erfolgt auf Grundlage unserer Verkaufs- und Lieferbedingungen.
Firmenbuch FN 187 60p / UID-Nr. ATU 314 701 00 / DVR 077 6858.



EN ISO 9001 u. EN ISO 14001
Zertifikate Nr. 20 100 5187 u. 20 104 9025
www.tuv.at

All electrodes with the following lot numbers are affected:

Kundenname Customer name	Produktbezeichnung/ Name of product	Lot Nummer/ Lot number
SCHILLER Médical SAS (FR)	0-21-0000 (DF66 / 50352)	30604-0772
SCHILLER Médical SAS (FR)	0-21-0000 (DF66 / 50352)	30731-0777
SCHILLER Médical SAS (FR)	0-21-0000 (DF66 / 50352)	30904-0773
SCHILLER Médical SAS (FR)	0-21-0000 (DF66 / 50352)	31023-0771
SCHILLER Médical SAS (FR)	0-21-0000 (DF66 / 50352)	31129-0770
SCHILLER Médical SAS (FR)	0-21-0000 (DF66 / 50352)	40312-0775
SCHILLER Médical SAS (FR)	0-21-0000 (DF66 / 50352)	40404-0773
SCHILLER Médical SAS (FR)	0-21-0000 (DF66 / 50352)	40424-0771
SCHILLER Médical SAS (FR)	0-21-0000 (DF66 / 50352)	40606-0776
SCHILLER Médical SAS (FR)	0-21-0000 (DF66 / 50352)	40627-0771
SCHILLER Médical SAS (FR)	0-21-0000 (DF66 / 50352)	40715-0772
SCHILLER Médical SAS (FR)	0-21-0000 (DF66 / 50352)	40915-0779
SCHILLER Médical SAS (FR)	0-21-0021 (DF66C / 50353)	30904-0774
SCHILLER Médical SAS (FR)	0-21-0021 (DF66C / 50353)	31104-0772
SCHILLER Médical SAS (FR)	0-21-0021 (DF66C / 50353)	31130-0770
SCHILLER Médical SAS (FR)	0-21-0021 (DF66C / 50353)	40312-0776
SCHILLER Médical SAS (FR)	0-21-0021 (DF66C / 50353)	40404-0774
SCHILLER Médical SAS (FR)	0-21-0021 (DF66C / 50353)	40415-0773
SCHILLER Médical SAS (FR)	0-21-0021 (DF66C / 50353)	40626-0977
SCHILLER Médical SAS (FR)	0-21-0021 (DF66C / 50353)	40825-0976
SCHILLER Médical SAS (FR)	0-21-0021 (DF66C / 50353)	40912-0973
SCHILLER Médical SAS (FR)	0-21-0021 (DF66C / 50353)	41015-0978
SCHILLER Médical SAS (FR)	W1404262 (DF67 / 50354)	30813-0772
SCHILLER Médical SAS (FR)	W1404262 (DF67 / 50354)	30905-0775
SCHILLER Médical SAS (FR)	W1404262 (DF67 / 50354)	40407-0770
SCHILLER Médical SAS (FR)	W1404262 (DF67 / 50354)	40627-0779
SCHILLER Médical SAS (FR)	W1404262 (DF67 / 50354)	40923-0777
Schiller AG (CH)	2.155062 (DF70 / 50463)	40204-0774
Schiller AG (CH)	2.155062 (DF70 / 50463)	40408-0770
Schiller AG (CH)	2.155062 (DF70 / 50463)	40731-0772
Schiller AG (CH)	2.155064 (DF70 / 50609)	30904-0795
GS	04325.2 (DF61 / 50125)	30822-0779
GS	04325.2 (DF61 / 50125)	31219-0776
GS	04325.2 (DF61 / 50125)	40507-0773
GS	05120.2 (DF68 / 50531)	30708-0777
GS	05120.2 (DF68 / 50531)	30822-0778
GS	05120.2 (DF68 / 50531)	31009-0773
GS	05120.2 (DF68 / 50531)	31121-0774
GS	05120.2 (DF68 / 50531)	40107-0771
GS	05120.2 (DF68 / 50531)	40213-0774
GS	05120.2 (DF68 / 50531)	40222-0773

GS	05120.2 (DF68 / 50531)	40320-0770
GS	05120.2 (DF68 / 50531)	40321-0770
GS	05120.2 (DF68 / 50531)	40324-0773
GS	05120.2 (DF68 / 50531)	40522-0779
GS	05120.2 (DF68 / 50531)	40704-0776
GS	05120.2 (DF68 / 50531)	40808-0773
GS	05120.2 (DF68 / 50531)	40923-0776
GS	05120.2 (DF68 / 50531)	41021-0778
Metrax	73672 (DF38 / 50395)	40211-0779
Metrax	73672 (DF38 / 50395)	40326-0776
Metrax	73672 (DF38 / 50395)	40731-0773
Metrax	18841 (DF63 / 50648)	40131-0778
Metrax	18841 (DF63 / 50648)	40821-0776
Metrax	18841 (DF63 / 50648)	40910-0776
GE	2059144-005 (DF69 / 50461)	30702-0778
GE	2059144-005 (DF69 / 50461)	40217-0776
GE	2059144-005 (DF69 / 50461)	40424-0772
GE	2059144-005 (DF69 / 50461)	30618-0771
GE	2059144-005 (DF69 / 50461)	30918-0775
GE	2059144-005 (DF69 / 50461)	31127-0772
GE	2059144-005 (DF69 / 50461)	31213-0771
GE	2059144-005 (DF69 / 50461)	40704-0775
GE	2059144-005 (DF69 / 50461)	40407-0777

Please quarantine these lot numbers.



Please report to us immediately all quantities of these products you have in stock or in the field using the attached form.

Request the necessary amount of electrodes according to your demand by your dealer. Upon receiving the replacement goods dispose immediately the affected electrodes by the recall.

Confirm the disposal on a written and signed company letterhead stating the lot number and the pieces.

Please also inform your customers and make sure that they also place all quantities of these products they have in stock or in the field in quarantine and report them using the attached form.

Kind regards

Quality Manager
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