

Object: Spes Medica Safety Notice for possible Non-Conformities to Steril Milano

Dear Customer/Distributor,

Following the communications of Steril Milano and the Ministry of Health (http://www.salute.gov.it/portale/news/p3_2_1_1_1.jsp?lingua=italiano&menu=notizie&p=dalministro&id=5365) on possible deviations of the parameters/processes defined for ethylene oxide sterilization, already validated and routinely used by Steril Milano; the company Spes Medica S.r.l. informs you that in the years 2019-2020-2021 has used the Steril Milano supplier only once in August 2020.

However only for safety reason If you have the following products in your stock, **we ask you to immediately block the sale and the use and, in case, to forward this request to your customers or sub-distributors. Please contact our Customer Service to send back to us the products, we will replace with another LOT number.**

REF	LOT	Description
LSE4246MCA075	LS20G3274I	Laryngeal Electrode
UE006	UR20F2702I	Urethral Electrode
LSE3463DCA200	LS20E2538I	Laryngeal Electrode
LSEPA09	LS20G3360I	Laryngeal Electrode
UE002	UR20F2699I	Urethral Electrode
D039045401	NN20E2370I	Disposable needle electrode for EEG and EMG
MN4013D101	MN20G3574I	Disposable needle electrode for EEG and EMG
MN4013D102	MN20G3575I	Disposable needle electrode for EEG and EMG
D039045401	NN20E2555I	Disposable needle electrode for EEG and EMG
MNCSC625DS	MN20G3135I	Disposable needle electrode for EEG and EMG
MNCSC625DST	MN20G3136I	Disposable needle electrode for EEG and EMG
SI3H0020S2526D	SI20F2956I	Disposable Stimulation Probe
TT03MN4013D/10	MN20F2990I	Disposable needle electrode for EEG and EMG
MN4018D152/2	MN20G3503I	Disposable needle electrode for EEG and EMG
MN4013D152	MN20G3504I	Disposable needle electrode for EEG and EMG
MN4013D15A/S	MN20B0735I	Disposable needle electrode for EEG and EMG
TFDN452531SB	MN20G3171I	Disposable needle electrode for EEG and EMG

We apologize for that, but we also want to underline that the sterilization process is an external process and does not depend directly on Spes Medica S.r.l .



For any request for clarification or support, do not hesitate to contact:

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Sure of your understanding, we look forward to your cooperation.

Best Regards

Eng. Giorgio Facco
Regulatory Affairs & Quality Assurance
Spes Medica Srl