

Casorezzo, 19th May 2021

To Whom it may concern

OBJECT: RECALL -- sterile surgical brush-sponge dry

With reference to our product NEX D1 DRY - sterilized by Ethylene Oxide treatment - we would like to inform that

Notified Body Kiwa Cermet Italia SpA, due to the *Incident Report* received by our former supplier of EtO sterilization service STERIL MILANO about a presumable manipulation of their sterilization processes, suggested a precautionary recall of the product in object on May, 3rd 2021.

The precautionary recall involves the following batches:

ND0498	NE0262
ND0500	NE0263
ND0503	NE0281
	NE0638
	NE0639
	NE0671

Therefore, we kindly ask your full support as follows:

- communicate to our Sales Office units you still have in stock for the above mentioned batches by Friday, May, 28th 2021;
- communicate to our Sales Office units still in stock at end-users for the above mentioned batches by Friday, May, 28th 2021.

With regards to goods already delivered to end-users, we will send the list of all the concerned batches to the National EU Competent Authorities for public consultation.

For additional clarifications, please contact tiziano.golzi@PDI-EMEA.com.

Thanks in advance for your collaboration.

Yours faithfully,

NEX MEDICAL ANTISEPTICS S.R.L.

