

MANUFACTURER STATEMENT

Manufacturer: MERCATOR MEDICAL S.A.
UL. H.MODRZEJEWSKIEJ 30
31-327 KRAKOW, POLAND

hereby informs that for non-sterile, nitrile examination and protective gloves available in the following brands:

nitrylex® befree

nitrylex® befree long

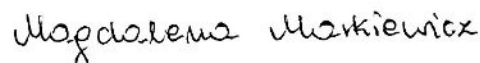
The 4-digit number of the notified body indicated next to the CE mark on the product packaging has changed. The change from CE 0598 to CE 2797 is the result of the transfer of the type conformity assessment procedure based on the quality assurance of the production process (Module D) in accordance with Regulation (EU) 2016/425, which is currently under the supervision of the notified body BSI Group The Netherlands B.V. with the number 2797.

At the same time, we declare that the continuity of supervision over the product as well as the production process has been maintained. The product complies with all applicable relevant European regulations and complies with the relevant product standards indicated in the Manufacturer's Declaration of Conformity.

Please be advised that while stocks last, both packaging labeling variants may still be available. Please download the relevant Declaration of Conformity available on www.mercatormedical.eu corresponding to the version of gloves you've purchased. In case of any doubt, please contact us via e-mail: BOK@pl.mercatormedical.eu.

Date and place of issue:
22.12.2021, Krakow

Sign on behalf of the Manufacturer:



Magdalena Markiewicz

Junior Product Documentation Specialist

MERCATOR MEDICAL S.A.
ul. Heleny Modrzejewskiej 30, 31-327 Kraków
tel. 12 66 55 400, fax 12 66 55 415
Rejestracja: Sąd Rejonowy dla Krakowa - Śródmieścia w Krakowie,
XI Wydział Gospodarczy KRS, KRS: 0000036244
Kapitał zakładowy (w całości wpłacony): 10.589.100 PLN
NIP: 677-10-36-424, REGON: 350967107
Numer BDO: 000056063
-6-