DECLARATION OF CONFORMITY

Examination gloves, non sterile
Basic UDI-DI: 8710685TF03001005Q3

As legal manufacturer, we

Medica Europe BV
Galliërsweg 20
5349 AT OSS
The Netherlands
Single Registration Number: NL-MF-000000118

hereby declare and ensure that this Declaration of Conformity is issued under our the sole responsibility and that the products, specified in the annexed product list, are in conformity with Annex II and Annex III of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

This declaration is supported by the Quality Management System certification based on standard EN ISO 13485:2016 with reference number: MD 567141 delivered by BSI Assurance UK Limited, originally registered on December 1, 2010.

We hereby also declare and ensure that the products, specified in the annexed product list, are in conformity with the provisions of Regulation (EU) 2016/425 and with the European standards EN420:2003+A1:2009, EN ISO 374-1:2016+A1:2018, EN 374-2:2014, EN 16523-1:2015+A1:2018, EN 374-4:2013, EN ISO 374-5:2016 and EN 388:2016 and are identical to the PPE which is subject to the EU-Type examination (Module B of the Regulation), under certificate number CE700538, issued by Notified Body:

BSI Group The Netherlands BV
John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands

The PPE is subject to the procedure set out in Module D of the Regulation under the supervision of BSI Group The Netherlands BV, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands, Notified Body number 2797.

Signed for and on behalf of Medica Europe BV:

Oss, 09 December 2020

D. van Beek
Manager Quality Assurance and Regulatory Affairs

PRODUCT LIST

Article number	Description	MDR Class	PPE Category
08896	SC NITRILE PLUS S	I	III
08897	SC NITRILE PLUS M	I	III
08898	SC NITRILE PLUS L	I	III
08899	SC NITRILE PLUS XL	I	III