MEDCARE
Medical protection

EU DECLARATION OF CONFORMITY

Manufacturer: Dongguan Grinvald Technology Co., Ltd.
Registered office: 401, Building #3, No 4 of Guangming New Village 2 Road, Dongcheng, Dongguan City, CN 523000
Authorised representative: Global Tooling Service s.r.o. (Reg. No. 063829)
Registered office: Varšavská 715/36, 120 00 Praha 2 – Vinohrady, CZ
Commercial registration No.: 06981607
SRN: CZ-AR-000002884
Product name: NBR Nitrile Examination Gloves
Name complement: MEDCARE, Nitra Force
Basic UDI-DI: GMN 859420829MEDCARETX
Intended purpose: Nitrile medical examination gloves are non-sterile and are used for performing medical examinations, diagnostic or therapeutic interventions, and for work with infectious medical material. These protect the patient and the user from contamination. The gloves are intended for single use.
Risk class of medical device: I
Risk category of personal protective equipment: III
Options: S (6), M (7), L (8), XL (9)
Medical Device Reference Number: 00935316
Harmonised standards applied: EN ISO 13485:2016, EN ISO 9001:2015, EN ISO 14971:2019, IEC 62366-1:2015(en), EN ISO 15223-1:2021, EN 455-1:2000, EN 455-2:2015, EN 455-3:2015, EN 16523-1:2015+A1:2018, EN ISO 374-1:2016+A1:2018, EN 420:2003+A1:2009, EN 374-2:2014, EN ISO 374-4:2019, EN ISO 374-5:2016, EN 1186-1:2002, EN1186-3:2002, EN 1186-14:2002, BS EN 13130-1:2004, BS EN12868:1999, 15223-1:2016D6124:06(2017), ASTM 6319, ASTM D5151-19, ASTM D6978-05(2019)

The manufacturer declares under its sole responsibility that the characteristics of the above mentioned medical device and personal protective equipment meet all requirements in accordance with Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices and Regulation (EU) 2016/425 of the European Parliament and of the Council on personal protective equipment and that this medical device and personal protective equipment is for the intended purpose of use safe, effective, and suitable for the provision of health care. The personal protective equipment type-examination (module B) was performed by the notified body SATRA Technology Europe Ltd. (2777). EU Type-Examination Certificate number: 2777/15456-02/E00-00. The PPE is subject to the conformity assessment procedure based on internal production control plus supervised product checks at random intervals (Module C2) under surveillance of the notified body SATRA Technology Europe Ltd. (2777).

Date: 11.10.2021
Location: Dongguan, China

Dr. Anna Grinvald, CEO