MEDCARE
Medical protection

GLOBAL TOOLING SERVICE SRO
Commercial registration No.: 06981607

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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.
Registered office: Na Folimance 2155/15, 120 00 Praha 2 - Vinohrady
Commercial registration No.: 06981607

Product name: Synthetic Nitrile Examination Gloves
Name complement: MEDCARE, Nitra Force
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, M, L, XL

Harmonised standards applied: EN ISO 13485:2016, EN ISO 9001:2015, EN ISO 14971:2019, IEC 62366-1:2015(en), EN ISO 15223-1:2016, 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, GB 4086.11-2016.

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

Date: 25 November 2020

Location: Dongguan, China

Anna Grinvald

Dr. Anna Grinvald, CEO

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