

EU DECLARATION OF CONFORMITY

Manufacturer:	Changzhou Universal Medical Equipment Co., Ltd
Registered office:	No. 6, Information Avenue, Xin Bei District, Changzhou City
European Representative:	Luxus Lebenswelt GmbH
Registered office:	Kochstr. 1, 47877, Willich Germany
Product name:	Nitrile Examination Gloves
Name complement:	Kleanse
Item No.:	WN-N001
Intended purpose:	Intended for single use and non-sterile, our Synthetic Nitrile Examination Gloves are used for performing medical examinations, diagnostic or therapeutic interventions. With a high protection percentage, these gloves are ideal for a working environment with infectious medical material.
Risk class of medical device:	Class I
Risk category of personal protective equipment:	III
Sizes:	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

Med Consulting SRL as the Kleanse Brand's EC Representative, Luxus Lebenswelt GmbH as the European Representative and the manufacturer declare under our sole responsibility that the characteristics of the above mentioned medical device and personal protective equipment meet all requirements in accordance to Annex IX of the Directive 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/Module C2) was performed by the notified body SATRA Technology Europe Ltd.(2777). EU Type-Examination Certificate number: 2777/15723-01/E00-00

Place and Date of Issue

Asti, 09th june 2021

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