



No Ordinary®

EU DECLARATION OF CONFORMITY

Manufacturer	Yradiant Global Pty Ltd
Address	Level 6/10 Herb Elliott Ave, Sydney Olympic Park, NSW, 2127
Single Registration Number	APP000053858
EU Authorized Representative	mdi Europa
Address	Langenhagener Str. 71 30855 Langenhagen Germany
Single Registration Number	DE-AR-000006218
Products covered	See Annex 1

We declare that the non-sterile, powder-free, nitrile examination gloves covered by this declaration and listed in Annex 1, whose intended use is to protect patients, users or third parties against diseases and provide temporary protection against bacteria, fungi, viruses and certain chemicals, can be used in the laboratory, medical and industrial sectors as well as in the domestic area by laypersons and healthcare users alike, are in conformity as PPE and medical devices with:

PPE Regulation (EU) 2016/425 as amended and with standards EN ISO 374-1:2016+A1:2018, EN ISO 374-5:2016 and EN ISO 21420:2020.

SATRA Technology Europe Limited (Notified Body N° 2777) performed the EU type-examination (Module B) and issued the EU type-examination certificate N° 2777/12470-05/ E06-01 for category III PPE,

is subject to the conformity assessment procedure set out in Module C2 of Regulation (EU) 2016/425 under the supervision of SATRA Technology Europe Limited, Bracetown Business Park, Clonee, Dublin 15 D15 YN2P, Republic of Ireland (Notified Body N° 2777).



and

Medical Device Regulation (EU) 2017/745 as amended and with standards EN 455-1:2020, EN 455-2:2015, EN 455-3:2015 and EN 455-4:2009 and are Class I self-declared according to Annex VIII, Rule 1 and 5 and are subject to conformity assessment procedure using technical documentation according to Annex II and Annex III



This declaration of conformity is issued under the sole responsibility of the manufacturer.

Done in Sydney, Australia, on 05 July 2023.

Steve Smith

Steve Smith (Aug 3, 2023 10:45 GMT+10)

Steve Smith
Managing Director
Yradiant Global Pty Ltd



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ANNEX 1

Product names	UDI-DI	GMDN code
No Ordinary single use non-sterile power-free Nitrile Gloves	9358016003487 (size XS)	56286
	9358016003494 (size S)	56286
	9358016003500 (size M)	56286
	9358016003517 (size L)	56286
	9358016003524 (size XL)	56286
	9358016003593 (size XXL)	56286