

Declaration of Conformity E3UC-HTL 13

Basic UDI-DI: 57440162E3UCJE

DECLARATION OF CONFORMITY

The device is in conformity with Medical Device Regulation (EU) 745/2017 and the Personal Protective Equipment Regulation (EU) 2016/425

	Fill in information if applicable
Name and address of Manufacturer	MediPart ApS Jernbanegade 75 5500 Middelfart Denmark
SRN Number of the Manufacturer	DK-MF-000003431
Basic UDI-DI	57440162E3UCJE
Reference number	MediPart E3UC Cosanum 171009200 171009201 171009202 171009203 171009204 171009300 171009301 171009302 171009303 171009304
Product name/Trade name	Nitrile Examination Gloves Powder Free CosaLine Nitrile Comfort White and Blue
Risk class (MDR)	Class I
Category (PPER)	CAT III
Intended Use	Protection against cross contamination
Reference to standards if applicable (MDR)	EN 455-1, EN 455-2, EN 455-3 and EN 455-4
Reference to standards if applicable (PPER)	EN 420, EN 374-1 and EN 374-5

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EU-Type certificate (PPER)	2777/10896-03/E03-01
Notified body name and number (if relevant) - PPER	2777

This EU Declaration of Conformity is issued under the sole responsibility of:

Middelfart, 2021.05.27


Rikke Nygaard