Declaration of Conformity E3UP-HTL 13
Basic UDI-DI: 57440162E3UPK8

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	57440162E3UPK8
Reference number	MediPart E3UP Cosanum 171005100 171005101 171005102 171005103 171005104
Product name/Trade name	Nitrile Examination Gloves Powder Free CosaLine Nitrile Elastik
Risk class (MDR)	Class I
Category (PPER)	CAT III
Intended use	Protection from 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
EU-Type certificate (PPER)	2777/10894-04/E05-01
Notified body name and number (if relevant) - PPER	2777

Jernbanegade 75-77
5500 Middelfart – Denmark
Contact: rikke@medipart.dk
Tel.: +45 2465 5885

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

Middelfart, 2021.05.27

Rikke Nygaard