

UKCA Declaration of Conformity

In accordance with The Medical Device Regulation 2002 No. 618 (UK) as amended.

Medical Device	Family: Examination gloves, non-sterile		
Catalogue number (REF)	Examination gloves made of latex, powder-free:		
	- Gentle Skin® sensitive (REF 1221RT)		
	- Gentle Skin® classic (REF 1221R)		
	- Gentle Skin® classic x-long (REF 1223)		
	- Gentle Skin® grip (REF 1221GRIP)		
	- Gentle Skin® compact (REF 1221I)		
	- Gentle Tec (REF 1229)		
	- Gentle Skin® HiRisk (REF 1228)		
	- Gentle Skin® Aloecare (REF 1231)		
	- Gentle Skin® black (REF 1224)		
	Examination gloves made of nitrile, powder-free:		
	- Nitril® 3000 (REF 1280)		
	- Nitril® 3000 X-Long Blue (REF 1282)		
	- Nitril® NextGen® (REF 1283)		
	- Nitril® BestGen® (REF 1286)		
	- Nitril® Magenta (REF 1287)		
	- Nitril® Black (REF 1284)		
	- Nitril® Viola (REF 1285)		
	- Nitril® Sensory® white (REF 2280)		
	- Nitril® Sensory® blue (REF 2283)		
	- Nitril® Sensory® violet blue (REF 2285)		
	Examination gloves made of vinyl, powder-free:		
	- Vinyl 2000 PF (REF 1251)		
	- Vinyl 2000 Stretch PF (REF 1253)		
	- Vinyl BlueGen (REF 1255)		
	The list of products which are alternatively marketed with other brand names (private label) and which are covered by this Declaration of Conformity are listed in Annexes 1 – 2.		
Basis UDI-DI	GMN42500164H002exglovesnsF2		
Intended use	The non-sterile examinations gloves are intended for the protection from contamination of patients and user.		
Medical device class according to Part II 7. [Annex IX]			
Chosen conformity assessment procedure	Part II 13.1 (as amended) [Annex VII]		



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Manufacturer	Meditrade GmbH Medipark 1 D-83088 Kiefersfelden
UK Responsible Person	Meditrade UK Ltd. 176-178 Brompton Road, London, SW3 1HQ
MHRA Registration Number	16399

We hereby declare in our own responsibility the conformity of the above medical devices with The Medical Device Regulation 2002 No. 618 (UK) as amended.

Meditrade hereby declares that medical devices covered by this declaration comply with this Regulation and, where applicable, with other relevant provisions which require the issuance of an UK/ declaration of conformity.

Kiefersfelden, 18.03.2022

Person responsible for regulatory compliance,

Martin Unterberg



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List of annexes:

Annex	Brand Owner	REF	Produkt	Meditrade-Produkt	REF
1	Unodent	CGN040 CGN041 CGN042 CGN043 CGN044	Nitrisoft Nitrile examination gloves	Nitril NextGen	1283
2	Quickco	CON1202 CON1203 CON1204	QSP Black Nitrile powder free gloves	Nitril Black	1284
		CON1102 CON1103 CON1104	QSP Blue Nitrile powder free gloves	Nitril NextGen	1283



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Annex 1

Medical Device	Family: Examination gloves, non-sterile	
Brand Owner	Unodent	
Catalogue number (REF)	Nitrile examination gloves, powder-free: - Nitrisoft nitrile examination gloves (REF CGN040, CGN041, CGN042, CGN043, CGN044)	
Base UDI-DI	GMN42500164H002exglovesnsF2	
Intended Use	The non-sterile examinations gloves are intended for the protection from contamination of patients and user.	
Medical device class according to Part II 7. [Annex IX]		



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Annex 2

Medical Device	,,,,,,,,,,,,,,		
Brand Owner			
Catalogue number (REF)	Nitrile examination gloves, powder-free: - QSP Black Nitrile powder free gloves(REF CON1202, CON1203, CON1204) - QSP Blue Nitrile powder free gloves(REF CON1102, CON1103, CON1104)		
Base UDI-DI	GMN42500164H002exglovesnsF2		
Intended Use	The non-sterile examinations gloves are intended for the protection from contamination of patients and user.		
Medical device class according to Part II 7. [Annex IX]			