



DICHIARAZIONE DI CORRISPONDENZA

SIR SAFETY SYSTEM S.p.A unipersonale

Soggetta a direzione
di SIR Holding S.r.l.

Sede Legale

Via dei Fornaciai, 9
06081 S.Maria degli Angeli
Assisi - Perugia - Italy

Partita IVA:

033 59 34 05 48

Telefono:

075 804.37.37 r.a.

Fax Commerciale:

075 804.37.47

Fax Amministrazione:

075 804.47.76

E-mail:

sir@sirsafety.com

Web Site:

www.sirsafety.com

Capitale Sociale:

Euro 3.500.000 i.v.

R.I. PG:

033 59 34 05 48

REA PG:

n° 28 36 20

Indirizzo PEC:

amm.ne@pec.sirsafety.com

Sede di Milano:

Viale Europa, 74
20090 Cusago (MI)

Telefono:

02 903.94.575 r.a.

Fax:

02 903.94.441

**AZIENDA CON SISTEMA
DI GESTIONE PER LA QUALITÀ
CERTIFICATO
UNI EN ISO 9001:2015**

La società:

SIR SAFETY SYSTEM SPA Unipersonale

Via dei Fornaciai, 9
06081 S.MARIA DEGLI ANGELI (PG)

Dichiara sotto la propria responsabilità, che il seguente Dispositivo di Protezione Individuale (DPI):

GUANTO ABENA CLASSIC NITRILE

Articolo **MA2121**

E' corrispondente all'articolo

Nitril Medical Examination Gloves, Powder-Free

Fabbricato da

ABENA A/S, Egelund 35, DK-6200 Aabenraa, Denmark

Indicato nella Dichiarazione allegata

S. MARIA DEGLI ANGELI 25/10/2021

Gino SIRCI

Amministratore Delegato
SIR SAFETY SYSTEM SPA UNIPERSONALE



EU Declaration of Conformity

Legal Manufacturer

- Name	ABENA A/S	www.abena.com
- Address	Egelund 35	Phone: +45 7431 1818
- Phone / fax / email / webpage	DK-6200 Aabenraa Denmark	Fax: +45 7462 9737 Mail: info@abena.com
- Single Registration Number (SRN), if applicable	DK-MF-000002482	

Medical Device(s)


- Basic UDI-DI	570353800MeNF-001-06006CU
- Product/trade name(s) and/or product code(s) (REF)/and or catalogue number	Nitril Medical Examination Gloves, Powder-Free
- Other ref. allowing identification (e.g. UDI-DI)	-
- Intended Purpose	Nitrile Examination gloves are intended to be worn by healthcare practitioners to protect patient and user from cross-contamination.
- Risk classification	Class 1 according to rule no. 1 and 5 in MDR annex VIII

Other information (if applicable)

- Common Specifications used for compliance	
- Notified Body name and identification no. and description of the conformity assessment procedure performed	SATRA Technology Europe Limited Bracetown Business Park Clonee D15YN2P Ireland
- Additional information	EU Type Examination Module B and On-going conformity Module C2 performed by notified body 2777, SATRA Technology Europe Limited. Issued EU Type Examination certificate number 2777/10648/E17-01
- Standards used to assure compliance	EU 2016/425, EN374-1:2016 Type B, EN374-4:2013, EN374-5:2016 Virus, EN16523-1:2015

The above mentioned manufacturer hereby declare that the above mentioned medical device(s) are compliant with the EU Regulation 2017/745 for Medical Devices and the EU legislations mentioned under "additional information".

This Declaration of Conformity is issued under the sole responsibility of the above mentioned manufacturer.

Name and Function: Khalid Elamri, Global Category Manager Signature 	Place and date of issue Aabenraa, DK, 11-05-2021
Abena, Egelund 35, DK-6200 Aabenraa	

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Appendix I, List of products

Product Name	Item no.	UDI-DI	Intended Purpose
Classic Nitril Examination gloves powder free blue colour 200 pcs and 100 pcs	1999902086-199992090 1999905271-1999905275	-	Protect patient and user from cross-contamination.

Appendix II, List of applicable standards used

Product Name	Standards used
Nitril Examination gloves powder free	EN 455-1:2002
Nitril Examination gloves powder free	EN 455-2:2015
Nitril Examination gloves powder free	EN 455-3:2015
Nitril Examination gloves powder free	EN 455-4:2009
Nitril Examination gloves powder free	EN374-1:2016
Nitril Examination gloves powder free	EN374-2:2003
Nitril Examination gloves powder free	EN374-4:2013
Nitril Examination gloves powder free	EN374-5:2016
Nitril Examination gloves powder free	EN16523-1:2015
Nitril Examination gloves powder free	EN420:2003

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