

DICHIARAZIONE DI CONFORMITA' CE

Sulla base del Reg. (UE) 2016/425 sui DPI

La sottoscritta:

PAPERLYNEN PAL CAPS SRL, Via Roma, 50, 55051 BARGA (LU)

Dichiara, in conformità all'Allegato IX del REGOLAMENTO (UE) 2016/425 e sotto la sua completa responsabilità, che i guanti LYNHAND PRO N460 (codici R6946001/3/5/7/9) sono conformi al Regolamento (UE) 2016/425, come DPI III Categoria.

La presente Dichiarazione di Conformità viene rilasciata sulla base del rispetto dei requisiti del Regolamento sui Dispositivi di Protezione Individuale (UE) 2016/425 per la Categoria III (Modulo D):

- La conformità al tipo basata sulla garanzia della qualità del processo di produzione sotto la sorveglianza dell'organismo notificato numero 2777 da parte di SATRA Technology Europe Ltd.
- L'organismo notificato SATRA Technology Europe Limited (2777) ha rilasciato il certificato di esame UE del tipo 2777/10470-06/E00-00 (data emissione 18/01/2022 – scadenza certificato 18/01/2027)

Fabbricante: Paperlynen Pal Caps s.r.l.

Indirizzo: Via Roma 50, 55051 Barga (LU), ITALIA

Nome prodotto: Guanti di protezione in nitrile LYNHAND PRO N460, senza polvere, clorurati, non sterili

Categoria di protezione: DPI III Categoria

Misure	Small	Medium	Large	X-Large
Codici articolo	R6946003	R6946005	R6946007	R6946009



Lista degli Standard e Regolamenti applicabili

No.	Regulation/ Standard Number	Regulation/ Standard Name
1	MDR (EU) 2017/745	Medical Device Regulation
2	PPE (EU) 2016/425	Personal Protective Equipment Regulation
3	ISO 13485: 2016	Medical devices - Quality management systems - Requirements for regulatory purposes
4	ISO 9001: 2015	Quality management systems – requirements
5	ISO 14971: 2019	Medical devices - application of risk management to medical devices
6	EN 455-1: 2020	Requirements and testing for freedom from holes
7	EN 455-2: 2015	Requirements and testing for physical properties
8	EN 455-3: 2015	Requirements and testing for biological evaluation
9	EN 455-4 : 2009	Requirements and testing for shelf life determination
10	ISO 10993-1: 2018	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
11	ISO 10993-5: 2009	Biological evaluation of medical devices – Part 5: Test for in vitro cytotoxicity
12	ISO 10993-10: 2010	Biological evaluation of medical devices – Part 10: Test for irritation and skin sensitization
13	ASTM F1671: 2013	Standard test method for resistance of materials used in protective clothing to penetration by blood-borne pathogens using phi-x174 bacteriophage penetration as a test system
14	ASTM D6319: 2019	Standard specification for nitrile examination gloves for medical application
15	EN ISO 20417: 2021	Medical devices - Information to be supplied by the manufacturer
16	ISO 15223-1: 2021	ISO 15223-1 Symbols to be used with information to be supplied by the manufacturer
17	ASTM D7160: 2016	Determination of expiration dating for medical gloves
18	ASTM D7161: 2016	Determination of real time expiration dating of mature medical gloves stored under typical warehouse conditions
19	ASTM D 6978-05: 2019	Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs

20	EN ISO 374-1: 2016+A1: 2018	Protective gloves against dangerous chemicals and micro-organisms - Part 1: Terminology and performance requirements for chemical risks
21	EN ISO 374-2: 2019	Protective gloves against dangerous chemicals and micro-organisms - Part 2: Determination of resistance to penetration
22	EN ISO 374-4: 2019	Protective gloves against chemicals and micro-organisms - Part 4: Determination of resistance to degradation by chemicals
23	EN ISO 374-5: 2016	Protective gloves against dangerous chemicals and micro-organisms - Part 5: Terminology and performance requirements for micro-organisms risks
24	EN 16523-1: 2015+A1: 2018	Determination of material resistance to permeation by chemicals - Part 1: Permeation by liquid chemical under conditions of continuous contact
25	EN ISO 21420: 2020	Protective gloves - General requirements and test methods

Rilasciato: Barga, 05 Giugno 2024

Scadenza: 04/06/2026

PAPERLYNEN PAL CAPS S.r.l.

Il legale rappresentante

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