EU Declaration of Conformity

to the 2017/745 Medical Device Regulation
2016/425 Personal Protective Equipment Regulation

We, Prosenso ApS, declare under our sole responsibility that the medical device stated below meets all provisions of the Medical Device Regulation (EU) 2017/745 and Personal Protective Equipment Regulation (EU) 2016/425.

Manufacturer:
Prosenso ApS
—
Address:
Gotfred Rodes Vej 2
2900 Charlottenlund, Danmark
—
Single Registration Number:
DK-MF-000043015
—
Product Name:
Latex Examination Gloves, Powder Free, Chlorinated, Non-Sterile
—
Product Group Code:
LO01
—
Product Size:
XS, S, M, L, XL (apply to all product codes)
—
Intended Purpose:
A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. Examination glove is intended for medical activities except surgery.

Device Classification:
(as per MDR 2017/745)
Class I under Rule 1 and 5 according to Annex VIII
—
Basic UDI-DI:
5745000094LO01VE
—
CE marking first applied:
May 2020
—
GMDN code and term:
47172 Hevea-latex examination/treatment glove, non-powdered, non-antimicrobial
—
EMDN/CND:
T010201 (Examination/ Treatment Gloves, Latex)
—
Conformity Assessment Route:
(As per MDR 2017/745)
Annexes II and III

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About this Declaration of Conformity

This Declaration of Conformity is issued on the basis of fulfilment the requirements of Annex IV of the Medical Device Regulation (EU) 2017/745 with:

- Quality Management System certification to EN ISO 13485: 2016 under the supervision of LiberoAssurance, certificate number DN3117001022131A
- Availability of technical documentation per Annex II and Annex III of the Medical Device Regulation (EU) 2017/745

This Declaration of Conformity is also issued on the basis of fulfilment the requirements of the Personal Protective Equipment Regulation (EU) 2016/425 for Category III (Module D):

- The conformity to type based on quality assurance of the production process under surveillance of the notified body number 2777 by SATRA Technology Europe Ltd.
- The EU Type-Examination Certificate number 2777/10467-08/E14-01

List of Applicable Regulations and Standards

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: 2024	Requirements and testing for physical properties
8	EN 455-3: 2023	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

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No.	Regulation/ Standard Number	Regulation/ Standard Name
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	ISO 10993-23: 2021	Symbols to be used with information to be supplied by the manufacturer
14	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
15	ASTM D3578: 2019	Standard specification for rubber examination gloves
16	EN ISO 20417: 2021	Medical devices - Information to be supplied by the manufacturer
17	ISO 15223-1: 2021	Symbols to be used with information to be supplied by the manufacturer
18	ASTM D7160: 2016	Determination of expiration dating for medical gloves
19	ASTM D7161: 2016	Determination of real time expiration dating of mature medical gloves stored under typical
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

DoC expires after 5 years.

Prosenso

Gotfred Rodes Vej 2
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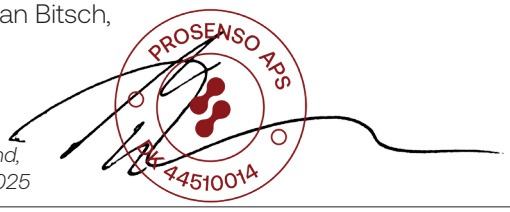
Denmark

Niels Kristian Bitsch,
CEO



Charlottenlund,
January 17 2025

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Annex

(Product Description)

Product Name (Device)	Product Code (KMAT)*	Product Specification Code**
Latex Examination Gloves, Powder Free, Chlorinated, Non-Sterile Latex Gloves, Prosenso, Pearl White	EWLTX50MST DLOFSOG	EWLTX50MST2-XS EWLTX50MST2-S EWLTX50MST2-M EWLTX50MST2-L EWLTX50MST2-XL

Product Code (KMAT)* means the specific code to identify the collective product design as a general code within the LO01 group. This Product Code (KMAT) is used to communicate in terms of contracts, general information, reports, and sales.

Product Specification Code** means the glove specification code for individual products used along with Product Code (KMAT). This Product Specification Code is also used to communicate in terms of contracts, approbations, and sales. With these detailed codes, it is possible to trace back individual designs and their specifications as agreed with the purchasing party.

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