Declaration of Conformity

Legal Manufacturer

Guilin HBM Health Protections, Inc.
No.1-2, Shuijing East Road, Economic and Technological Development Area, Guilin,China
SRN：CN-MF-000033439

Authorized Representative in the EU:

HBM Medical
Coliemore House, Coliemore Road,
Dalkey, Co. Dublin, Ireland.
SRN：IE-AR-000031279

Brand owner :

Evercare Medical AB
29 Tagenevägen, SE-425 37
Hisings Kärra,Sverige

declare under our sole resporsibility that following CE marked products, all belonging to

- **Class II** according to annex VIII of directive EU 2017/745(MDR) Rule 7, .
- **Category III** according to the **Regulation (EU) 2016/425** on personal protective equipment.

Intended Purpose:
Latex surgical gloves are for medical purposes intended to be worn on s the hands, primarily in surgical environments, to provide a barrier against potentially infectious materials and other contaminants. The gloves are sterile and for single use.

Basic UDI- DI : 697178707SGNRUF

Item number (REF)	Trade and product name
EMTPC 55	Evercare® Latex Surgical Glove 5.5,
EMTPC 60	Evercare® Latex Surgical Glove 6.0
EMTPC 65	Evercare® Latex Surgical Glove 6.5
EMTPC 70	Evercare® Latex Surgical Glove 7.0
EMTPC 75	Evercare® Latex Surgical Glove 7.5
EMTPC 80	Evercare® Latex Surgical Glove 8.0
EMTPC 85	Evercare® Latex Surgical Glove 8.5
EMTPC 90	Evercare® Latex Surgical Glove 9.0
EMLUG 55	Evercare® Latex Surgical Underglove 5.5
EMLUG 60	Evercare® Latex Surgical Underglove 6.0
EMLUG 65	Evercare® Latex Surgical Underglove 6.5
EMLUG 70	Evercare® Latex Surgical Underglove 7.0
EMLUG 75	Evercare® Latex Surgical Underglove 7.5
EMLUG 80	Evercare® Latex Surgical Underglove 8.0
EMLUG 85	Evercare® Latex Surgical Underglove 8.5
EMLUG 90	Evercare® Latex Surgical Underglove 9

We declare the conformity of the above-mentioned products by issuing this EU Declaration of Conformity after drawing up the technical documentation set out in Annexes II and III of Regulation (EU) 2017/745, in accordance with Article 52(7) of Regulation (EU) 2017/745. They are in conformity with Personal Protective Equipment Regulation (EU) 2016/425, under Category III risk set out in Annex I.

EN ISO 13485	Medical Devices - Quality management systems - Requirements for regulatory purposes
EN ISO 21420	Protective gloves – General requirements and test methods.
EN ISO 16523	Determination of resistance of materials to permeation by liquids and gases.
EN 455	Protective glove. General requirements and test method
EN 455 -1	Medical Gloves for single use part 1 - Requirements and testing for freedom from holes
EN 455 -2	Medical Gloves for single use part 2 - Requirements and testing for physical properties
EN 455- 3	Medical Gloves for single use part 3- Requirements and testing for biological evaluation
EN 455-4	Medical Gloves for single use part 4-Requirements and testing for shelf life determination
EN ISO 374	Protextive gloves against chemicals and micro-organism.
EN ISO 374-1	Part 1 - Terminology and performance requirements for chemical risks.
EN ISO 374-2	Part 2: Determination of resistance to penetration.
EN ISO 374-3	Part 3: Determination of resistance to permeation by chemicals.
EN ISO 374-4	Part 4: Determination of resistance to degradation by chemicals.
EN ISO 374-5	Part 5 : Terminology and performance requirements for micro-organisms risks.

The product(s) under the conformity assessment procedure **Modul D** under surveillance of the notified body 2777 SATRA Technology Europe Limited, Bracetown Business Park, Clonee, D15YN2P,Republic of Ireland. SATRA Reference: STE2013276.

The product(s) under the supervision of Notified Body BSI Group The Netherlands B.V., located at Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands, with CE number 2797 and Registration No. MDR 747912 R000.

Pu lei

Pu lei/Quality Director

23.03.2025 Guilin, China