

EU Type Examination Certificate

This is to certify that:

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

Holds Certificate Number:

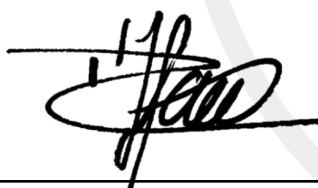
CE 754433

In respect of:

Natural Rubber Latex surgical gloves for personal protection.
Model: MTPC.

on the basis that BSI carried out the relevant Type Examination procedures under the requirements with the Regulation (EU) 2016/425 of the European Parliament and Council relating to Personal Protective Equipment Regulation (PPE) Annex V (Module B) and meets the relevant health and safety requirements specified in Annex II

For and on behalf of BSI, a Notified
Body for the above Regulation
(Notified Body Number 2797):



Drs. Dave Hagenaaers, Managing Director

First Issued: 2022-07-26

Latest Issue: 2022-07-26

Effective Date: 2022-07-26

Expiry Date: 2027-07-26

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EU Type Examination Certificate

No. CE 754433

Product Specification

PPE Category: Category III - Complex.

Technical Specification: Type Examination for PPE model listed in this certificate is conducted to Annex II of the Regulation (EU) 2016/425 and based on the following European Standards:

EN ISO 21420:2020 Protective gloves. General requirements and test methods.

EN ISO 374-1:2016+A1:2018 Protective gloves against dangerous chemicals and micro-organisms. Terminology and performance requirements for chemical risks.

EN ISO 374-2:2019 Protective gloves against dangerous chemicals and micro-organisms. Determination of resistance to penetration. (Test Method)

EN ISO 374-4:2019 Protective gloves against dangerous chemicals and micro-organisms. Determination of resistance to degradation by chemicals. (Test Method)

EN ISO 374-5:2016 Protective gloves against dangerous chemicals and micro-organisms. Terminology and performance requirements for micro-organisms risks.

EN 16523-1:2015+A1:2018 Determination of material resistance to permeation by chemicals. Permeation by potentially hazardous liquid chemicals under conditions of continuous contact. (Test Method)

ISO 16604:2004 Clothing for protection against contact with blood and body fluids. Determination of resistance of protective clothing materials to penetration by blood-borne pathogens. Test method using Phi-X174 Bacteriophage. (Test Method)

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No. CE 754433

Product Specification

Model:	MTPC		
Product Code:	MTPC-55, MTPC-60, MTPC-65, MTPC-70, MTPC-75, MTPC-80, MTPC-85, MTPC-90.		
Classification:	Protective gloves for use against micro-organisms and general applications.		
Description:	A sterile, powder-free, cream colour natural rubber latex surgical glove. The glove is hand specific and is anatomically shaped, textured finish.		
Performance:	Resistance to chemical permeation to EN ISO 374-1:2016+A1:2018		
	Type B Chemical protection (Test method EN 16523-1:2015+A1:2018)		
	Chemical		Level
	40% Sodium Hydroxide (K)		6
	30% Hydrogen Peroxide (P)		6
	37% Formaldehyde (T)		6
	Resistance to degradation to EN ISO 374-4:2019		
	Tested for all chemicals listed above.		
	Protection against micro-organism risks to EN ISO 374-5:2016		
	Bacteria and fungi (Test method EN ISO 374-2:2019)		Pass
Viruses (Test Method ISO 16604:2004)		Pass	
General requirements for gloves to EN ISO 21420:2020			
Dexterity:	Level 5		
pH:	Pass		
Size Range:	5.5, 6, 6.5, 7, 7.5, 8, 8.5, 9		

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Certificate Administration Details

Technical File Reference: HBM/PPE-01 Version: A/0

Certificate Amendment record:

Issue Date	Comments	BSI Review No.
July 2022	First issue, model MTPC.	2797:22:3493131

Certificate validity

The Certificate holder is responsible for ensuring that the Notified Body is advised of changes to any aspect of the overall process utilised in the manufacture of the product, failure to do so could invalidate the Certificate in respect of product manufactured following the introduction of such changes.

The validity of the Certificate for the products is also dependent on the maintenance of the EU Conformity to Type based on Quality Assurance of the Production Process, Annex VIII (Module D), as referenced on BSI issued Certificate CE 754434.

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