


## EU-Declaration of Conformity No. 2215

MEDICAL DEVICE REGULATION (EU) 2017/745  
PERSONAL PROTECTIVE EQUIPMENT REGULATION (EU) 2016/425

Class I according to MD Regulation (EU) 2017/745/ Category III according to PPE Regulation (EU) 2016/425

<b>Artikel:</b> 2215 <b>teXXor</b>	 © BIG Arbeitsschutz GmbH
<b>Model:</b> Nitril-Disposable Gloves, powder-free	

### Brand owner:

BIG Arbeitsschutz GmbH  
Königsberger Str. 6  
D - 21244 Buchholz i.d.N.  
Germany

### Legal Manufacturer

HARPS Investment Asia Pte. Ltd  
9 Straits View, #08-10A Marina One West  
Tower,  
Singapore 018937 Singapore  
SRN:SG-MF-000001645

### Authorized representative in the EU

HARPS Europe GmbH  
Wiedner Guertel 9-13  
1100 Vienna Austria  
SRN:AT-AR-000040870

**We hereby declare under sole responsibility that the CE marked product described above conforms to the requirements of the regulation for medical devices (EU) 2017/745.**

Declaration based on Annex IV. Classification according to rule 5, Annex VIII. The conformity assessment is based on Annex II.




EN 455-1:2020	Medical gloves for single use - Part 1: Requirements and testing for freedom from holes
EN 455-2:2015	Medical gloves for single use - Part 2: Requirements and testing for physical properties
EN 455-3:2015	Medical gloves for single use - Part 3: Requirements and testing for biological evaluation
EN 455-4:2009	Medical gloves for single use - Part 4: Requirements and testing for shelf life determination

**We hereby declare under sole responsibility that the CE marked product described above conforms with the applicable provisions of Regulation (EU) 2016/425 on personal protective equipment and is identical to the personal protective equipment which is subject to EU Type Examination Certificate No. 2777/11464-03/E06-02 issued by:**

SATRA Technology Europe Ltd.  
Bracetown Business Park  
Clonee, Dublin D15 YN2P  
Ireland  
Kenn-Nr.: 2777

The products are subject to the procedure set out in Annex VII (Module C2) of Regulation (EU) 2016/425 under the supervision of

SATRA Technology Europe Ltd.  
Bracetown Business Park  
Clonee, Dublin D15 YN2P  
Ireland  
Kenn-Nr.: 2777

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

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The technical specification is available at:



[www.big-arbeitsschutz.de](http://www.big-arbeitsschutz.de)

This document was issued on: 17.05.2024/Rev.04  
This document is applicable until: 28.08.2028

## BIG Arbeitsschutz GmbH

Malte Kuhring  
- Managing Director -