

## IZJAVA EU O SKLADNOSTI CE DECLARATION OF CONFORMITY

**Ime proizvajalca**  
*Name of manufacturer*

**UAB Kasko Group I Kid-Man™**  
**SRN: LT-MF-000007721**

**Naslov proizvajalca**  
*Address of manufacturer*

A. Vivulskio g. 12D, 03221, Vilnius,  
Lietuva (Litva)

**Na lastno odgovornost izjavljamo, da je medicinski pripomoček**  
**Declares on our own responsibility, that Medical Device**

**Ime medicinskega  
pripomočka**

*Medical device name*

**Nesterilne rokavice za enkratno  
uporabo iz lateksa**

*Disposable latex gloves*

**Model / Model**

**KID-MAN**

**Osnovni / Basic UDI-DI**

**477903163LTGLL6**

| REF                                                   | Velikosti / Sizes    | Barva / Color |
|-------------------------------------------------------|----------------------|---------------|
| LTGLXS100; LTGLS100; LTGLM100;<br>LTGLL100; LTGLXL100 | XS (5-6) – XL (9-10) | Bela / White  |

**skladen z Uredbo (EU) 2017/745 Evropskega parlamenta in Sveta o medicinskih pripomočkih, spremembi Direktive 2001/83/ES, Uredbe (ES) št. 178/2002 in Uredbe (ES) št. 1223/2009 ter razveljavitvi Direktiv Sveta 90/385/EGS in 93/42/EGS in 93/42/EGS ter razvrščen kot medicinski pripomoček razreda I v skladu z merili pravila 1 Priloge VIII k Uredbi (EU) 2017/745.**

*Complies to Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices and amending Directive 2001/83/EC, Regulation (EC) No 178/2002, Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC and is classified as Class I medical device in accordance with criteria set out in Annex VIII, Rule 1 of Regulation (EU) 2017/745.*

**Zgoraj opisani izdelki so prav tako razvrščeni kot osebna varovalna oprema (OVO) kategorije III in so v skladu z Uredbo (EU) 2016/425 Evropskega parlamenta in Sveta z dne 9. marca 2016 o osebni varovalni opremi.**

*The products described above are also classified as Personal Protective Equipment (PPE) Category III and comply with Regulation (EU) 2016/425 of the European Parliament and the Council of 9<sup>th</sup> March 2016 on Personal Protective Equipment*

**Uporabljeni usklajeni standardi / Applied harmonized standards:**

|                                  |                                                                                                                                                                                                                                                                                                                                  |
|----------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>EN 455-1:2020</b>             | Medicinske rokavice za enkratno uporabo – 1. del: Zahteve in preskusi za ugotavljanje odsotnosti lukenj<br>Medical gloves for single use - Part 1: Requirements and testing for freedom from holes                                                                                                                               |
| <b>EN 455-2:2015</b>             | Medicinske rokavice za enkratno uporabo – 2. del: Zahteve in preskusi za ugotavljanje fizikalnih lastnosti<br>Medical gloves for single use - Part 2: Requirements and testing for physical properties                                                                                                                           |
| <b>EN 455-3:2015</b>             | Medicinske rokavice za enkratno uporabo – 3. del: Zahteve in preskušanje za biološko ovrednotenje<br>Medical gloves for single use - Part 3: Requirements and testing for biological evaluation                                                                                                                                  |
| <b>EN 455-4:2009</b>             | Medicinske rokavice za enkratno uporabo – 4. del: Zahteve in preskusi za določanje roka uporabnosti<br>Medical gloves for single use - Part 4: Requirements and testing for shelf life determination                                                                                                                             |
| <b>EN 16523-1:2015+A1:2018</b>   | Ugotavljanje odpornosti materiala proti pronicanju kemikalij – 1. del: Pronicanje potencialno nevarnih tekočih kemikalij pri pogojih neprestanega stika<br>Determination of material resistance to permeation by chemicals - Part 1: Permeation by potentially hazardous liquid chemicals under conditions of continuous contact |
| <b>EN ISO 21420:2020</b>         | Varovalne rokavice – Splošne zahteve in preskusne metode<br>Protective gloves — General requirements and test methods                                                                                                                                                                                                            |
| <b>EN ISO 15223-1:2021</b>       | Medicinski pripomočki – Simboli za označevanje podatkov, ki jih mora podati dobavitelj – 1. del: Splošne zahteve<br>Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements                                                                                      |
| <b>EN ISO 374-1:2016+A1:2018</b> | Varovalne rokavice za zaščito pred nevarnimi kemikalijami in mikroorganizmi – 1. del: Izrazje in zahtevane lastnosti za zaščito pred kemičnimi tveganji<br>Protective gloves against dangerous chemicals and micro-organisms - Part 1: Terminology and performance requirements for chemical risks                               |
| <b>EN ISO 374-2:2019</b>         | Varovalne rokavice za zaščito pred nevarnimi kemikalijami in mikroorganizmi – 2. del: Ugotavljanje odpornosti proti penetraciji<br>Protective gloves against dangerous chemicals and micro-organisms - Part 2: Determination of resistance to penetration                                                                        |
| <b>EN ISO 374-4:2019</b>         | Varovalne rokavice za zaščito pred nevarnimi kemikalijami in mikroorganizmi – 4. del: Ugotavljanje odpornosti proti razkroju zaradi kemikalij<br>Protective gloves against dangerous chemicals and micro-organisms - Part 4: Determination of resistance to degradation by chemicals                                             |
| <b>EN ISO 374-5:2016</b>         | Varovalne rokavice za zaščito pred nevarnimi kemikalijami in mikroorganizmi – 5. del: Izrazje in zahtevane lastnosti za zaščito pred tveganji, povezanimi z mikroorganizmi<br>Protective gloves against dangerous chemicals and micro-organisms - Part 5: Terminology and performance requirements for micro-organisms risks     |
| <b>ISO 9001:2015</b>             | Sistem vodenja kakovosti<br>Quality Management System                                                                                                                                                                                                                                                                            |

Vilna, 19. 07. 2024

**MARTYNAS VAINUTIS**

Generalni direktor / Managing Director

Ime in podpis / Name and signature