

# EU Declaration of Conformity

**Manufacturer:** Prenger Healthcare B.V.  
**Company name:** Prenger Healthcare B.V.  
**Street:** Lange Kleiweg 14  
**City:** Rijswijk  
**Postal code:** 2288 GK  
**State/county/province:** South Holland  
**Country:** The Netherlands  
**Contact:** +31 70 2040 440  
**Email:** info@prengerhealthcare.com

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**Object of declaration:** Prenger 2001 Surgical Masks with Earloop  
**Model:** 2001

**The object of the declaration described above is in conformity with the relevant community harmonization legislation:**

Meet the applicable provisions of the CE (EU) 2017/745 (MDR) on medical devices for class 1. Also relates to Council Directive 93/42/EEC of 14 June 1993 on medical devices.

**European Representative:**

Lotus NL B.V.  
Koningin Julianaplein 10, first floor 2595 AA, The Hague Netherlands.

**References to the relevant harmonised standards used or references to the specifications in relation to which conformity is declared:**

EN 14683:2019+AC:2019 — Medical face masks — Requirements and test methods,  
EN ISO 15223-1:2016 — Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements

**Signed for and on behalf of Prenger Healthcare B.V.:**

**First name, last name:** Peter Prenger  
**Title:** Founder  
**Place, date:** The Hague, 01-12-2021