

# EU DECLARATION OF CONFORMITY

(In accordance with EN ISO/IEC 17050-1)

We,

Medisana GmbH  
Jagenbergstr. 19  
41468 Neuss  
Germany

**medisana**

declare as manufacturer and distributor in Europe under sole responsibility that the below mentioned products are conform to  
Personal Protective Equipment (PPE) Regulation (EU) 2016/425

**Product identification**

Brandname: **medisana**  
Model. Nr.: RM 100  
Type Nr. D13003 / D13003AC  
Art. No. 33333 / 99940



**Other specifications:**

Particle filtering mask,  
Category III, FFP2 NR/KN 95

**The conformity assessment has been done by  
Name and address:**

**Medical Device Branch of Zhangzhou Easepal Industrial co., Ltd.**  
4th Floor of Building #7, No.228, Jiaosong Road,  
Taiwanese Investment Zone, Zhangzhou,  
Fujian, China

**according to  
EU Community Legislation**

**Personal Protective Equipment (PPE) Regulation (EU) 2016/425**  
**Annex II Category III** in connection with  
**Annex V (Module B EU Type Examination Certification)**  
Cert. No.: CE-PC-200323-021-01-9A and  
**Annex VII (Module C2 Production Monitoring)**  
Cert- No.: CE-PC-200323-021-FPC-A

**Harmonised standards**

**Personal protective equipment**  
**EN 149:2001+A1:2009**  
National Quality Supervision and Testing Center for Personal Protective  
Equipment (Beijing) test report: 2020(D)-0628

**Certified by Notified Body**

**CCQS Certification Service Ltd. (CE 2834)**  
Block 1 Blanchardstown Corporate Park,  
Ballycoolin Road,  
Blanchardstown,  
Dublin 15, D15 AKK1

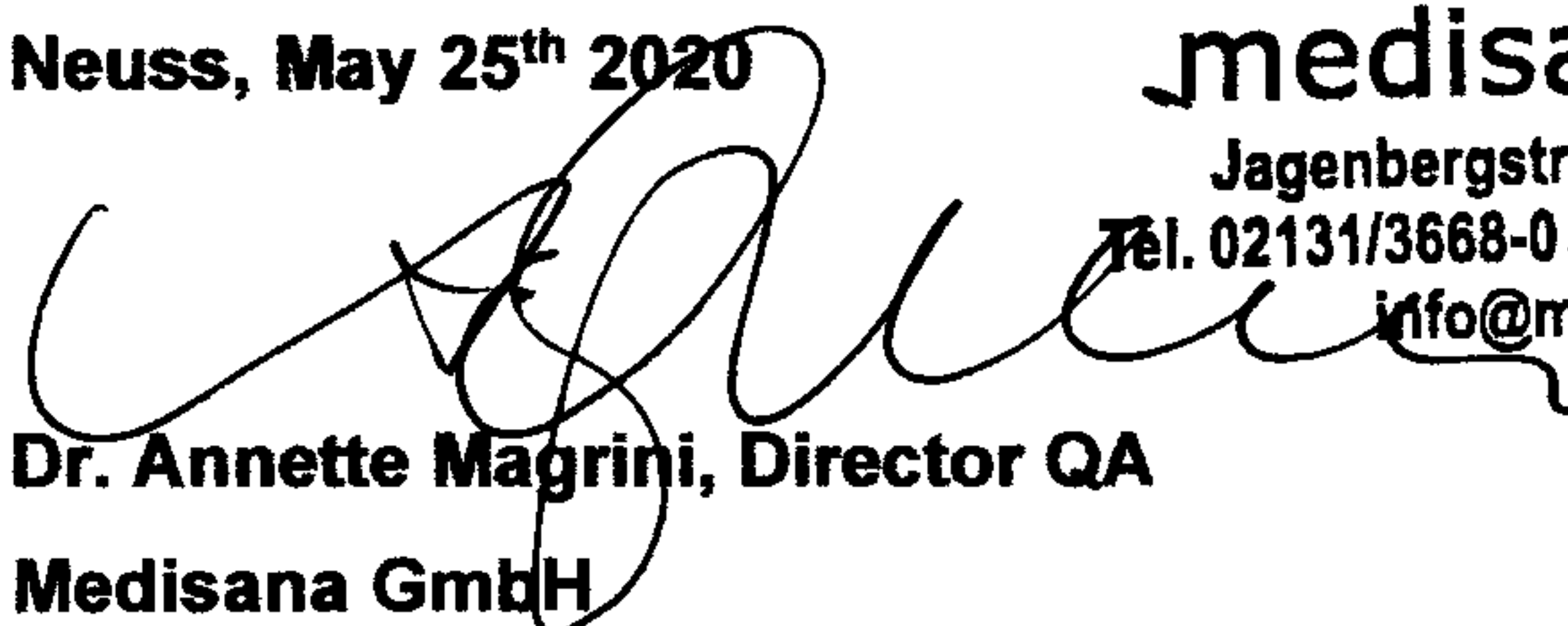
**This declaration is valid since May 25<sup>th</sup> 2020 until August 19<sup>th</sup> 2020**

**Place and date of issue: Neuss, May 25<sup>th</sup> 2020**

**medisana GmbH**

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Signature:



Name, function:

**Dr. Annette Magrini, Director QA**

Company name:

**Medisana GmbH**