EU DECLARATION OF CONFORMITY

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

We,

Medisana GmbH
Jagenbergstr. 19
41468 Neuss
Germany

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)
CCQS Cert. No: CE-PC-200323-021-01-9B and
Annex VII (Module C2 Production Monitoring)
Cert- No.: CE-PC-200323-021-FPC-B

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 20th 2020 until May 19th 2021

Place and date of issue: **Neuss, July17th 2020**

Signature:

medisana GmbH
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Name, function: **Dr. Annette Magrini, Director QA**

Company name: **Medisana GmbH**