

EU DECLARATION OF CONFORMITY

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

Name and address of **MedisanaGmbH**
importer and responsible Jagenbergstr. 19
distributor 41468 Neuss
in Europe Germany

THIS DECLARATION OF CONFORMITY IS ISSUED UNDER THE SOLE RESPONSIBILITY OF:

Name and address of **Medical Device Branch of Zhangzhou**
manufacturer: **EasepalIndustrial co., Ltd.**
4th Floor of Building #7, No.228,Jiaosong Road,
Taiwanese Investment Zone, Zhangzhou,
Fujian, China



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

The conformity assessment according to the essential requirements has been done by Easepal 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)**
CCQS 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 ReportNo.: 2020(D)-0628

Other specifications: **Particle filtering mask, Category III, FFP2 NR/KN 95**

In cooperation with

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

This declaration is valid until August 19th 2021

SIGNED FOR AND ON BEHALF OF:

Place and date of issue: Zhangzhou, 20Aug 2020
Signature: 
Name, function: 
Company name: **Medical Device Branch of Zhangzhou Easepal Industrial co., Ltd.**