Module B EU Type-Examination Certificate

For the requirements of PPE Regulation 2016/425

Certificate No.: CE-PC-200902-632-01-9B

Certificate holder:	**Medisana GmbH** Carl-Schurz-Str.2, 41460 NEUSS, Germany
Product:	**Particle Filtering Half Mask** Detailed product description listed in the Annex
Model(s):	RM100
Standard(s):	EN 149:2001+A1:2009 Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking
Issue date:	2020-10-07
Revision date:	2021-04-29
Expiry date:	2025-05-19

The product(s) on this certificate and the Technical File have been assessed and found to be in conformance with the applicable Essential Health and Safety Requirements in Annex II of the PPE regulation 2016/425.
Any changes to the design, manufacturing location or manufacture of the PPE product certified here must be advised to CCQS Certification Services Limited for review.
CE marking shall not be applied until the requirements of all the PPE Regulation 2016/425 and relevant EN Harmonised standards and/or Technical specifications have been met.
If the certified product is Category III then this certificate is only valid if used in conjunction with Conformity Assessment against Module C2 or Module D.
This certificate remains the property of CCQS and maybe withdrawn at any time if it is considered that the equipment is no longer in conformity with the requirements of the PPE Regulation 2016/425.

CE

Approved by Ireland Government as a Notified Body for CE Marking No.2834

ISO 17065 INAB ACCREDITED PRODUCT CERTIFICATION DETAILED IN SCOPE REG NO.6028

Approved by:

CCQS Ireland Certification

Owen Bian - Director

CCQS Certification Services Limited
Block 1 Blanchardstown Corporate Park, Ballycoolin Road, Blanchardstown, Dublin15, D15 AKK1, Ireland
Tel: +00 353 1 588 6920 Website: www.ccqs.co.uk E-mail: verify@ccqs.ie
If in any doubt about the integrity of this certificate, please contact CCQS by email to verify.

Module B EU Type-Examination Certificate

Annex

For the requirements of PPE Regulation 2016/425

Certificate No.: CE-PC-200902-632-01-9B

Applicable standards and specification:
EN 149:2001+A1:2009 Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking

Model reference	Product description
RM100	Folding filtering half mask fitted with ear loop and head harness retaining clip, no valves, internal metal nose clip Mask body color: White or Black variant Classification: FFP2 NR

Certificate Revision	Revision date	Revision details
A	2020-10-07	Initial issue
B	2021-04-29	Addition of mask body colour Black and change license holder address plus Technical file updates for change to address

CCQS Ireland Certification

CE

CCQS Certification Services Limited
Block 1 Blanchardstown Corporate Park, Ballycoolin Road, Blanchardstown, Dublin15, D15 AKK1, Ireland
Tel: +00 353 1 588 6920 Website: www.ccqs.co.uk E-mail: verify@ccqs.ie
If in any doubt about the integrity of this certificate, please contact CCQS by email to verify.

Certificate of Module C2 production monitoring for equipment within the scope of Personal Protective Equipment Regulation (EU) 2016/425 Category III

FPC Certificate No.: CE-PC-200902-632-FPC-B

Certificate holder:	**Medisana GmbH** Carl-Schurz-Str.2, 41460 NEUSS, Germany
Manufacturing location:	4th Floor of Building #7, No.228, Jiaosong Road, Taiwanese Investment Zone, Zhangzhou, Fujian, China
The scope of the certification for:	**The manufacture of respiratory protective device** See annex for articles covered by this certificate
Valid from:	2020-10-05
Revision date:	2021-04-29
To:	2023-05-19

CCQS Certification Services Limited in its role as a Notified Body for PPE Regulation, is monitoring that the manufacturer is producing PPE in conformity with the type described in the EU type-examination certificate and associated technical file and which satisfies the Essential Health and Safety Requirements of the Regulation.
The equipment covered by this certificate is listed in the accompanying schedule. This certificate is not complete and has no validity without the accompanying schedule and revision index.
The manufacturer is hereby authorized to affix our Notified Body number, 2834, to each item of PPE mentioned in the schedule which accompanies this certificate whilst this certificate remains valid.
This certificate and the accompanying schedule remain the property of CCQS and maybe withdrawn or revised at any time if CCQS considers that the equipment is no longer in conformity with the requirements of the Regulation.

CE

Approved by Ireland Government
as a Notified Body
for CE Marking No.2834

ISO 17065 INAB ACCREDITED PRODUCT CERTIFICATION DETAILED IN SCOPE REG NO.6028

Approved by:

Owen Bian - Director

CCQS Ireland Certification

CCQS Certification Services Limited
Block 1 Blanchardstown Corporate Park, Ballycoolin Road, Blanchardstown, Dublin15, D15 AKK1, Ireland
Tel: +00 353 1 588 6920 Website: www.ccqs.co.uk E-mail: verify@ccqs.ie
If in any doubt about the integrity of this certificate, please contact CCQS by email to verify.

Schedule of Module C2 production monitoring for equipment within the scope of Personal Protective Equipment Regulation (EU) 2016/425 Category III

Schedule to CCQS FPC Certificate No.: CE-PC-200902-632-FPC-B

Product reference and description		Reference standard
Particle Filtering Half Mask	Model: RM100	EN 149:2001+A1:2009

Certificate Revision	Revision date	Revision details
A	2020-10-05	Initial issue
B	2021-04-29	Extension of certificate's validity following Module C2 assessment and change the address

This schedule has no validity without the accompanying certificate.
This schedule and the accompanying certificate remain the property of CCQS and maybe withdrawn or revised at any time if CCQS considers that the equipment is no longer in conformity with the requirements of the Regulation.

CCQS Ireland Certification

CE

CCQS Certification Services Limited
Block 1 Blanchardstown Corporate Park, Ballycoolin Road, Blanchardstown, Dublin15, D15 AKK1, Ireland
Tel: +00 353 1 588 6920 Website: www.ccqs.co.uk E-mail: verify@ccqs.ie
If in any doubt about the integrity of this certificate, please contact CCQS by email to verify.

EU-KONFORMITÄTSERKLÄRUNG

EU DECLARATION OF CONFORMITY

(Gemäß/*in accordance with* EN ISO/IEC 17050-1)

DIESE KONFORMITÄTSERKLÄRUNG WIRD UNTER DER ALLEINIGEN VERANTWORTUNG ERSTELLT VON:
THIS DECLARATION OF CONFORMITY IS ISSUED UNDER THE SOLE RESPONSIBILITY OF:

Name und Anschrift des Herstellers: *Name and address of manufacturer:*	**medisana GmbH** Carl-Schurz-Str.2 41460 Neuss Deutschland / *Germany*
Produktidentifikation: *Product identification:*	**Markenname/** *brandname* **medisana** **Modell. Nr./** *model.no.* **RM 100** **Artikel Nr./** *art. no* **33333 / 33334 / 33335 / 33337**



Die Konformitätsbewertung nach den wesentlichen Anforderungen wurde gemäß
The conformity assessment according to the essential requirements has been done according to

EU-Rechtsvorschriften der Gemeinschaft: *EU-Community Legislation:*	**Verordnung über persönliche Schutzausrüstung (PSA) (EU) 2016/425** *Personal Protective Equipment (PPE) Regulation (EU) 2016/425* **Anhang II Kategorie III** in Verbindung mit *Annex II Category III in connection with* **Anhang V (Modul B EU-Baumusterprüfungsbescheinigung)** *Annex V (Module B EU Type Examination Certification)* CCQS Cert.-Nr.: CE-PC-200902-632-01-9B und **Anhang VII (Modul C2 Produktionsüberwachung)** *Annex VII (Module C2 Production Monitoring)* CCQS Cert-Nr.: CE-PC-200902-632-FPC-B
Harmonisierte Normen: *harmonized standards*:	**Persönliche Schutzausrüstung** **EN 149:2001+A1:2009** *Personal Protective Equipment* *EN 149:2001+A1:2009* Nationales Qualitätsüberwachungs- und Prüfzentrum für persönliche Schutzausrüstung (Peking) - Test Report Nr: 2021(D)-0628 *National Quality Supervision and Testing Center for Personal Protective Equipment (Beijing) -Test Report No.: 2020(D)-0628, 2020(F)-0591*
Weitere Spezifikationen: *further specifications*:	**Partikelfiltermaske, Kategorie III, FFP2 NR** *Particle filtering half mask, Category III, FFP2 NR*
In Zusammenarbeit mit Benannter Stelle: *in corporation with:* *Notified Body:*	**CCQS Certification Service Ltd. (CE 2834)** Block 1 Blanchardstown Corporate Park, Ballycoolin Road, Blanchardstown Dublin 15, D15 AKK1

Diese Erklärung ist gültig bis zum 19. May 2023
This declaration is valid until May 19th 2023

UNTERZEICHNET FÜR UND IM NAMEN VON:
SIGNED FOR AND BEHALF OF:

Ort und Datum der Ausstellung *Place and date* of issue:	Neuss, 27.05.2021 *2021 May 27th*
Unterschrift/ *Signature:*	
Name, Funktion *Name and function:*	**Thomas Hollefeld,** **Geschäftsführer,** *General Manager*
Firmenname/*Company name:*	**Medisana GmbH.**

medisana GmbH
Carl-Schurz-Str. 2 41460 Neuss
Tel. 02131/3668-0 Fax 02131/3668-5095
info@medisana.com

EU-KONFORMITÄTSERKLÄRUNG

EU DECLARATION OF CONFORMITY

(Gemäß/*in accordance with* EN ISO/IEC 17050-1)

DIESE KONFORMITÄTSERKLÄRUNG WIRD UNTER DER ALLEINIGEN VERANTWORTUNG ERSTELLT VON:
THIS DECLARATION OF CONFORMITY IS ISSUED UNDER THE SOLE RESPONSIBILITY OF:

Name und Anschrift des Herstellers: *Name and address of manufacturer:*	**medisana GmbH** Jagenbergstr. 19 41468 Neuss Deutschland / *Germany*
Produktidentifikation: *Product identification:*	**Markenname/** *brandname* **medisana** **Modell. Nr./** *model.no.* **RM 100** **Artikel Nr./** *art. no* **33333 / 33335 / 33337**



Die Konformitätsbewertung nach den wesentlichen Anforderungen wurde gemäß
The conformity assessment according to the essential requirements has been done according to

EU-Rechtsvorschriften der Gemeinschaft: *EU-Community Legislation:*	**Verordnung über persönliche Schutzausrüstung (PSA) (EU) 2016/425** *Personal Protective Equipment (PPE) Regulation (EU) 2016/425* **Anhang II Kategorie III** in Verbindung mit *Annex II Category III in connection with* **Anhang V (Modul B EU-Baumusterprüfungsbescheinigung)** *Annex V (Module B EU Type Examination Certification)* CCQS Cert.-Nr.: CE-PC-200902-632-01-9A und **Anhang VII (Modul C2 Produktionsüberwachung)** *Annex VII (Module C2 Production Monitoring)* CCQS Cert-Nr.: CE-PC-200902-632-FPC-A
Harmonisierte Normen: *harmonized standards:*	**Persönliche Schutzausrüstung** **EN 149:2001+A1:2009** *Personal Protective Equipment* *EN 149:2001+A1:2009* Nationales Qualitätsüberwachungs- und Prüfzentrum für persönliche Schutzausrüstung (Peking) - Test Report Nr: 2020(D)-0628 *National Quality Supervision and Testing Center for Personal Protective Equipment (Beijing) -Test Report No.: 2020(F)-0591*
Weitere Spezifikationen: *further specifications:*	**Partikelfiltermaske, Kategorie III, FFP2 NR** *Particle filtering half mask, Category III, FFP2 NR*
In Zusammenarbeit mit Benannter Stelle: *in corporation with:* *Notified Body:*	**CCQS Certification Service Ltd. (CE 2834)** Block 1 Blanchardstown Corporate Park, Ballycoolin Road, Blanchardstown Dublin 15, D15 AKK1

Diese Erklärung ist gültig bis zum 19. May 2021
This declaration is valid until May 19th 2021

UNTERZEICHNET FÜR UND IM NAMEN VON:
SIGNED FOR AND BEHALF OF:

Ort und Datum der Ausstellung *Place and date* of issue:	Neuss, 27.01.2021
Unterschrift/ *Signature:*	
Name, Funktion *Name and function:*	**Thomas Hollefeld,** **Geschäftsführer,** *General Manager*
Firmenname/*Company name:*	**Medisana GmbH.**

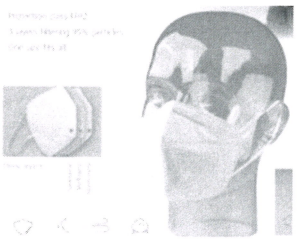
EU-KONFORMITÄTSERKLÄRUNG

EU DECLARATION OF CONFORMITY

(Gemäß/*in accordance with* EN ISO/IEC 17050-1)

DIESE KONFORMITÄTSERKLÄRUNG WIRD UNTER DER ALLEINIGEN VERANTWORTUNG ERSTELLT VON:
THIS DECLARATION OF CONFORMITY IS ISSUED UNDER THE SOLE RESPONSIBILITY OF:

Name und Anschrift des Herstellers: *Name and address of manufacturer:*	**medisana GmbH** Jagenbergstr. 19 41468 Neuss Deutschland / *Germany*
Produktidentifikation: *Product identification:*	**Markenname/** *brandname* **medisana** **Modell. Nr./** *model.no.* **RM 100** **Artikel Nr./** *art. no* **33333 / 33335**



Die Konformitätsbewertung nach den wesentlichen Anforderungen wurde gemäß
The conformity assessment according to the essential requirements has been done according to

EU-Rechtsvorschriften der Gemeinschaft: *EU-Community Legislation:*	**Verordnung über persönliche Schutzausrüstung (PSA) (EU) 2016/425** *Personal Protective Equipment (PPE) Regulation (EU) 2016/425* **Anhang II Kategorie III** in Verbindung mit *Annex II Category III in connection with* **Anhang V (Modul B EU-Baumusterprüfungsbescheinigung)** *Annex V (Module B EU Type Examination Certification)* CCQS Cert.-Nr.: CE-PC-200902-632-01-9A und **Anhang VII (Modul C2 Produktionsüberwachung)** *Annex VII (Module C2 Production Monitoring)* CCQS Cert-Nr.: CE-PC-200902-632-FPC-A
Harmonisierte Normen: *harmonized standards:*	**Persönliche Schutzausrüstung** **EN 149:2001+A1:2009** *Personal protective equipment* *EN 149:2001+A1:2009* Nationales Qualitätsüberwachungs- und Prüfzentrum für persönliche Schutzausrüstung (Peking) - Test Report Nr: 2020(D)-0628 *National Quality Supervision and Testing Center for Personal Protective Equipment (Beijing) -Test Report No.: 2020(D)-0628*
Weitere Spezifikationen: *further specifications:*	**Partikelfiltermaske, Kategorie III, FFP2 NR** *Particle filtering half mask, Category III, FFP2 NR*
In Zusammenarbeit mit Benannter Stelle: *in corporation with:* *Notified Body:*	**CCQS Certification Service Ltd. (CE 2834)** Block 1 Blanchardstown Corporate Park, Ballycoolin Road, Blanchardstown Dublin 15, D15 AKK1

Diese Erklärung ist gültig ab Lot 2010G PO 6539 bis zum 19. May 2021
This declaration is valid from lot 2010G PO 6539 until May 19th 2021

UNTERZEICHNET FÜR UND IM NAMEN VON:
SIGNED FOR AND BEHALF OF:

Ort und Datum der Ausstellung *Place and date* of issue:	Neuss, 05.11.2020
Unterschrift/ *Signature:*	
Name, Funktion *Name and function:*	**Thomas Hollefeld,** **Geschäftsführer,** *General Manager*
Firmenname/*Company name:*	**Medisana GmbH.**

medisana GmbH
Jagenbergstr. 19 41468 Neuss
Tel. 02131/3668-0 Fax 02131/3668-5095
info@medisana.de

EU-KONFORMITÄTSERKLÄRUNG

EU DECLARATION OF CONFORMITY

(Gemäß/*in accordance with* EN ISO/IEC 17050-1)

Name und Anschrift des Importeurs und Händlers in Europa *Name and address of importer and distributor responsible in Europe*	**medisana GmbH** Jagenbergstr. 19 41468 Neuss Deutschland *Germany*

DIESE KONFORMITÄTSERKLÄRUNG WIRD UNTER DER ALLEINIGEN VERANTWORTUNG ERSTELLT VON:

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

Name und Anschrift des Herstellers: *name and address of manufacturer:*	**Medical Device Branch of Zhangzhou Easepal Industrial co., Ltd.** 4. Floor of Building #7, Nr.228, Jiaosong Road, Taiwanesische Investment Zone, Zhangzhou, Fujian, China
Produktidentifikation: *product identification*	**Markenname:** **medisana** ***brandname*** **Modell. Nr.:** **RM 100** ***model.no.:*** **Typ Nr:** **D13003 / D13003AC** ***type no.:*** **Artikel Nr.** **33333 / 99940** ***art. no.***



Die Konformitätsbewertung nach den wesentlichen Anforderungen wurde von Easepal gemäß
The conformity assessment according to the essential requirements has been done by Easepal according to

EU-Rechtsvorschriften der Gemeinschaft *EU Community Legislation*	**Verordnung über persönliche Schutzausrüstung (PSA) (EU) 2016/425** *Personal Protective Equipment (PPE) Regulation (EU) 2016/425* **Anhang II Kategorie III** in Verbindung mit *Annex II Category III in connection with* **Anhang V (Modul B EU-Baumusterprüfungsbescheinigung)** *Annex V (Module B EU Type Examination Certification)* CCQS Cert.-Nr. / *CCQS Cert. no.:* CE-PC-200323-021-01-9B und / *and* **Anhang VII (Modul C2 Produktionsüberwachung)** *Annex VII (Module C2 Production Monitoring)* CCQS Cert.-Nr. / *CCQS Cert. no.:* CE-PC-200323-021-FPC-B
Harmonisierte Normen *Harmonised standards*	**Persönliche Schutzausrüstung EN 149:2001+A1:2009** *Personal protective equipmentEN 149:2001+A1:2009* National Quality Supervision and Testing Center for Personal Protective Equipment (Beijing) -Test Report Nr./*no.*: 2020(D)-0628

Diese Konformitätserklärung wurde über die ProductIP Compliance-Plattform

EU-KONFORMITÄTSERKLÄRUNG

EU DECLARATION OF CONFORMITY

(Gemäß/*in accordance with* EN ISO/IEC 17050-1)

Weitere Spezifikationen: *Other specifications:*	**Partikelfiltermaske, Kategorie III, FFP2 NR/KN 95** *Particle filtering mask, Category III, FFP2 NR/KN 95*
In Zusammenarbeit mit *in cooperation with:*	
Benannte Stelle: *Notified Body*	**CCQS Certification Service Ltd. (CE 2834)** Block 1 Blanchardstown Corporate Park, Ballycoolin Road, Blanchardstown Dublin 15, D15 AKK1

Diese Erklärung ist gültig bis zum 19. August 2021
This declaration is valid until August 19th 2021

UNTERZEICHNET FÜR UND IM NAMEN VON:
SIGNED FOR AND ON BEHALF OF:

Ort und Datum der Ausgabe: *Place and date of issue:*	Zhangzhou, 1 September 2020
Unterschrift: *Signature*	
Name, Funktion: *Name, function:*	**Lianzi Zhou** **Quality Manager**
Firmenname: *Company name:*	**Medical Device Branch of Zhangzhou Easepal Industrial co., Ltd.**