

EU-Konformitätserklärung *EU Declaration of Conformity*

Name und Anschrift des Herstellers/
Name and Address of Manufacturer:

MAVIG GmbH
Stahlgruberring 5
81829 Munich
Germany

Für die Ausstellung dieser EU-Konformitätserklärung trägt MAVIG GmbH die alleinige Verantwortung und bestätigt, dass die nachfolgend genannten Produkte die Anforderungen der Verordnung (EU) 2016/425 für Persönliche Schutzausrüstung sowie der Verordnung (EU) 2017/745 für Medizinprodukte erfüllen.

This EU declaration of conformity is issued under the sole responsibility of MAVIG GmbH who confirms that the products mentioned below meet the provision of the Regulation (EU) 2016/425 on personal protective equipment as well as of the Regulation (EU) 2017/745 on medical devices.

Produktgruppe/
Product group:

RA - Röntgenschutzkleidung Anwender
RA - Radiation Protective Clothing Medical

Zweckbestimmung/
Intended use:

Strahlenschutz für Anwender/Bediener/Patienten dient – im Röntgenröhrenspannungsbereich von 50 - 150 kV bzw. 50 - 110 kV – dem Schutz vor ionisierender Strahlung.

X-ray protection for operators/users/patients protects against ionizing radiation – in the X-ray tube voltage range of 50 - 150 kV or 50 - 110 kV

Produktbezeichnung/
Product name:

Siehe Annex 1 – Modellname-Tabelle
See Annex 1 - Model names table

Angewandte Normen/
Applied standards:

IEC 61331-1:2014
IEC 61331-3:2014

Basis-UDI-DI/ *Basic UDI-DI:*

4251339906440WV

Anforderungen an/ *Requirements for:*

Verordnung/
Directive:

Persönliche Schutzausrüstung/
Personal Protective Equipment
(EU) PPE 2016/425

Medizinprodukte/
Medical Devices
(EU) MDR 2017/745

Einmalige Registrierungsnummer/
Single registration number (SRN):

N/A

DE-MF-000006207

MAVIG GmbH
X-Ray Protection and
Medical Suspension Systems

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Trade-Register Munich
HRB-No. 76 403

Managing Directors:
Christian Stoian
Alexia Stoian-Lepère
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Kategorie/ Category:	Kategorie III	Klasse I, Regel 1
Klasse und Regel/ Class and rule:	Category III	Class I, Rule 1
EU-Baumusterprüfung durch benannte Stelle/ EU type-examination by notified body:	NB 0302 ANCCP Certification Agency S.R.L. Via dello Struggino 6 57121 Livorno (LI) – Italy	N/A
EU-Baumusterprüfung Zertifikat Nr./ EU type-examination Certificate:	PPE-2971-23482-Cert PPE-3088-23726-Cert (Levio Edition)	N/A
Konformitätsbewertungsverfahren/ Conformity assessment procedure:	Anhang I (Kategorie III, Punkt d); Anhang VIII (Modul D) durch NB 0302 <i>Annex I (Category III, point d); Annex III (Module D) by NB 0302</i>	MDR, Art 52 (7)

Diese Erklärung wurde ausgestellt von/
This statement was issued by:



Irene Madl – Head of Regulatory Management

Ort und Datum der Ausstellung/
Place and date of issue:

Munich, 2026-03-11

Annex I:

Modellname-Tabelle/ Model Names Table

Explanation

Abbreviation:	Meaning:	Explanation:
STD	Standard	Standard product with no changes
SON	Special Order Item	Standard product with custom changes
LVO	Levio® Edition	Optimized product (additional protection panel)
MAS	Made to Measure	A customized product tailored to the user's individual size

Model	Model name (like on the label):
RA614-STD	Schilddrüsen-/Sternumschutz RA614-STD/ Thyroid Shield Model RA614-STD
RA614-SON	Schilddrüsen-/Sternumschutz RA614-SON/ Thyroid Shield Model RA614-SON
	Rundumschutz RA631-STD Kostüm/ Allround Protective Model RA631-STD Costume
RA631-STD	Rundumschutz RA631-STD Kostüm-West/ Allround Protective Model RA631-STD Costume-Vest
	Rundumschutz RA631-STD Kostüm-Rock/ Allround Protective Model RA631-STD Costume-Skirt
	Rundumschutz RA631-STD Victoria-West/ Allround Protective Model RA631-STD Victoria-Vest

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RA631-SON	Rundumschutz RA631-SON Kostüm/ <i>Allround Protective Model RA631-SON Costume</i> Rundumschutz RA631-SON Kostüm-Weste/ <i>Allround Protective Model RA631-SON Costume-Vest</i> Rundumschutz RA631-SON Kostüm-Rock/ <i>Allround Protective Model RA631-SON Costume-Skirt</i> Rundumschutz RA631-SON Victoria-Weste/ <i>Allround Protective Model RA631-SON Victoria-Vest</i>
RA631-LVO	Rundumschutz RA631-LVO Kostüm/ <i>Allround Protective Model RA631-LVO Costume</i> Rundumschutz RA631-LVO Kostüm-Weste/ <i>Allround Protective Model RA631-LVO Costume-Vest</i> Rundumschutz RA631-LVO Kostüm-Rock/ <i>Allround Protective Model RA631-LVO Costume-Skirt</i> Rundumschutz RA631-LVO Victoria-Weste/ <i>Allround Protective Model RA631-LVO Victoria-Vest</i>
RA631-MAS	Rundumschutz RA631-MAS Kostüm/ <i>Allround Protective Model RA631-MAS Costume</i> Rundumschutz RA631-MAS Kostüm-Weste/ <i>Allround Protective Model RA631-MAS Costume-Vest</i> Rundumschutz RA631-MAS Kostüm-Rock/ <i>Allround Protective Model RA631-MAS Costume-Skirt</i> Rundumschutz RA631-MAS Victoria-Weste/ <i>Allround Protective Model RA631-MAS Victoria-Vest</i>
RA632-STD	Rundumschutz-Mantel RA632-STD Synergy/ <i>Coat Model RA632-STD Synergy</i>
RA632-SON	Rundumschutz-Mantel RA632-SON Synergy/ <i>Coat Model RA632-SON Synergy</i>
RA632-LVO	Rundumschutz-Mantel RA632-LVO Synergy/ <i>Coat Model RA632-LVO Synergy</i>
RA632-MAS	Rundumschutz-Mantel RA632-MAS Synergy/ <i>Coat Model RA632-MAS Synergy</i>
RA636-STD	Rundumschutz-Mantel RA636-STD Victoria/ <i>Coat Model RA636-STD Victoria</i>
RA636-SON	Rundumschutz-Mantel RA636-SON Victoria/ <i>Coat Model RA636-SON Victoria</i>
RA636-LVO	Rundumschutz-Mantel RA636-LVO Victoria/ <i>Coat Model RA636-LVO Victoria</i>
RA636-MAS	Rundumschutz-Mantel RA636-MAS Victoria/ <i>Coat Model RA636-MAS Victoria</i>
RA640-STD	Frontschuttschürze RA640-STD Basic/ <i>Front Apron Model RA640-STD Basic</i>
RA640-SON	Frontschuttschürze RA640-SON Basic/ <i>Front Apron Model RA640-SON Basic</i>
RA640-MAS	Frontschuttschürze RA640-MAS Basic/ <i>Front Apron Model RA640-MAS Basic</i>
RA641-STD	Frontschuttschürze RA641-STD Extended/ <i>Front Apron Model RA641-STD Extended</i>
RA641-SON	Frontschuttschürze RA641-SON Extended/ <i>Front Apron Model RA641-SON Extended</i>
RA641-MAS	Frontschuttschürze RA641-MAS Extended/ <i>Front Apron Model RA641-MAS Extended</i>
RA645-STD	Frontschutz RA645-STD Twice/ <i>Front Protective Model RA645-STD Twice</i>
RA645-SON	Frontschutz RA645-SON Twice/ <i>Front Protective Model RA645-SON Twice</i>
RA645-MAS	Frontschutz RA645-MAS Twice/ <i>Front Protective Model RA645-MAS Twice</i>
RA650-STD	Frontschuttschürze RA650-STD Ergonomic/ <i>Front Apron Model RA650-STD Ergonomic</i>
RA650-SON	Frontschuttschürze RA650-SON Ergonomic/ <i>Front Apron Model RA650-SON Ergonomic</i>
RA650-MAS	Frontschuttschürze RA650-MAS Ergonomic/ <i>Front Apron Model RA650-MAS Ergonomic</i>
RA660-STD	Frontschuttschürze RA660-STD Comfort/ <i>Front Apron Model RA660-STD Comfort</i>
RA660-SON	Frontschuttschürze RA660-SON Comfort/ <i>Front Apron Model RA660-SON Comfort</i>
RA660-LVO	Frontschuttschürze RA660-LVO Comfort/ <i>Front Apron Model RA660-LVO Comfort</i>
RA660-MAS	Frontschuttschürze RA660-MAS Comfort/ <i>Front Apron Model RA660-MAS Comfort</i>

Modellvarianten/ *Model versions:*

RA614-STD	RA614-SON	RA614522KL21	RA614522MA21	RA614525KL21
RA614525MA21	RA614527KL21	RA614527MA21	RA614528KL21	RA614528MA21
RA614529KL21	RA614529MA21	RA614530KL21	RA614530MA21	RA614531KL21
RA614531MA21	RA614532KL21	RA614532MA21	RA614522KL41	RA614522MA41

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RA614527KL41	RA614527MA41	RA614528KL41	RA614528MA41	RA614529KL41
RA614529MA41	RA614531KL41	RA614531MA41	RA614534KL41	RA614534MA41
RA614535KL41	RA614535MA41	RA614536KL41	RA614536MA41	RA614537KL41
RA614537MA41	RA614538KL41	RA614538MA41	RA631-STD	RA631-SON
RA631-LVO	RA631-MAS	RA632-STD	RA632-SON	RA632-LVO
RA632-MAS	RA636-STD	RA636-SON	RA636-LVO	RA636-MAS
RA640-STD	RA640-SON	RA640-MAS	RA641-STD	RA641-SON
RA641-MAS	RA645-STD	RA645-SON	RA645-MAS	RA650-STD
RA650-SON	RA650-MAS	RA660-STD	RA660-SON	RA660-LVO
RA660-MAS				

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