

MAVIG GmbH • Stahlgruberring 5 • 81829 Munich • Germany

To whom it may concern,

München, 30th June 2026

Statement Letter NON-MEDICAL DEVICE

Herewith we, MAVIG GmbH, manufacturer of X-Ray Protection and Medical Suspension Systems, with a headquarter in Munich, Germany, Stahlgruberring 5, D-81829, confirm that the products listed below:

Item	Product Name:
BR130	BR - Radiation Protective Glasses
Intended use	
Radiation protective glasses and visors are personal protective equipment for operators, when radiation are used in the radiologic tube voltage range of 50 kV - 150 kV. The PSA products are specially designed for use in medical diagnostics.	

DGS90-99	Radiation Protection Window
Intended use	
Radiation protective installation windows serve the on-site radiation protection of medical personnel, patients and third parties on site. The products are designed for applications in air-conditioned health care facilities, such as clinics, hospitals and doctors' practices. The products are used exclusively by medical professionals such as physicians and assistants.	

have been manufactured by MAVIG GmbH including packaging and quality control, according to international rules and standards and have passed all relevant quality tests and inspections.

The listed products have no medical intended use, therefore are not classified as a medical device according to (EU) MDR 2017/745.

MAVIG GmbH is certified according to EN ISO 13485:2016/A11:2021.

With kind regards,



MAVIG GmbH
 Stahlgruberring 5
 81829 München
 Tel. (0 89) 4 20 96 - 0

i.A. Slavica Georgiev
Regulatory Management

MAVIG GmbH
X-Ray Protection and
Medical Suspension Systems

Company Address
Stahlgruberring 5
81829 Munich
Germany

Post Box
Postfach 820362
81803 Munich
Germany

Phone
+49 (0) 89 / 420 96 - 0

Fax
+49 (0) 89 / 420 96 - 200

e-Mail
info@mavig.com

Web
www.mavig.com

Bank Accounts
HypoVereinsbank Munich
(EUR Account)
IBAN: DE80 7002 0270
1620 2253 00
SWIFT-BIC: HYVEDEMMXXX

HypoVereinsbank Munich
(USD Account)
IBAN: DE34 7002 0270
0880 2292 30
SWIFT-BIC: HYVEDEMMXXX

Postbank Munich
IBAN: DE12 7001 0080
0071 3748 07
SWIFT-BIC: PBNKDEFFXXX

Trade-Register Munich
HRB-No. 76 403

Managing Directors
Christian Stoian
Alexia Stoian-Lepère
Philip Milbredt

VAT-ID No.:
DE 811268845