

Certificate Number US19/81841517



The quality management system of
**MIPM Mammendorfer Institut
für Physik und Medizin GmbH**

Oskar-von-Miller Straße 6,
Mammendorf, 82291, Germany
Dun & Bradstreet D-U-N-S identification number: 32-441-6379

has been audited against the criteria stated below and found to conform to those criteria for the scope contained in this certificate

MDSAP(ISO 13485:2016)

Australia:
Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure [including design]

Brazil:
RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009

Canada:
Medical Devices Regulations – Part 1 SOR 98/282

Japan:
MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act

United States:
21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D

For the following activities and devices

Design and development, manufacture and servicing physiological patient monitoring system for the determination of physiological pressures used during investigations in magnetic resonance imaging

This certificate is valid from
Effective Date: 2019-04-10 until Expiry Date: 2022-04-09
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 2021-10-25
Issue 1. Certified since 2019-04-10

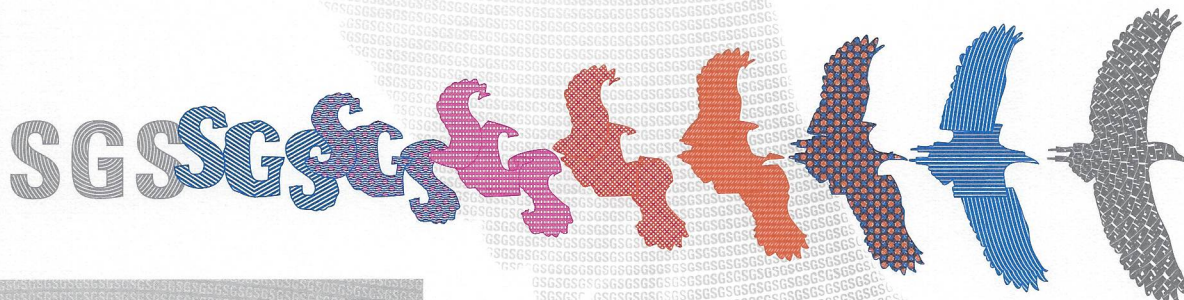
Authorised by J Hall
Business Manager

SGS United Kingdom Ltd
202B Worle Parkway, Weston-super-Mare, BS22 6WA, UK
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

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