

UKCA Certificate - Full Quality Assurance System

Part II of The Medical Devices Regulations 2002, Annex II excluding Section 4 [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]

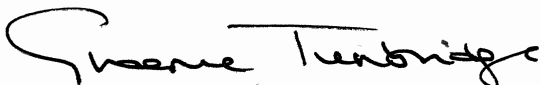
No. **UKCA 759368**
Issued To: **Medartis AG**
Hochbergerstrasse 60E
Basel
4057
Switzerland

In respect of:

Design, manufacture and final inspection of fixation and osteosynthesis systems for use in extremities and oral and maxillofacial surgery and associated instrumentation for connection to an active device.

On the basis of our examination of the quality assurance system under the requirements of Part II of the Medical Devices Regulations 2002, Annex II excluding Section 4 [as modified by Part II of Schedule 2A to The Medical Devices Regulations 2002]. The quality assurance system meets the requirements of the regulation. For the placing on the market of class III products an Annex II (modified as described above) Section 4 certificate is required.

For and on behalf of BSI, an Approved Body for the above Regulation (Approved Body Number 0086):



Graeme Tunbridge, Senior Vice President Medical Devices

First Issued: **2022-08-09**

Date: **2023-07-26**

Expiry Date: **2024-05-26**

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Supplementary Information to UKCA 759368

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Number	Device Name	Intended purpose per IFU
Class IIb		
35685, 46646, 46647, 56642, 61573, 61669, 61670 and 61671	APTUS: For the wrist, hand, forearm, elbow, foot, ankle, shoulder.	The fixation systems are intended for temporary fixation, correction, or stabilization of bones.
46646, 46647, 47930, 56642 and 61573	MODUS: For the mandible and mid-face.	The fixation and osteosynthesis systems are intended for use in oral and craniomaxillofacial surgery.
Class IIa		
MD 0106 MD 0401	Instruments for fixation and osteosynthesis systems	---
MD 0402	Arch bars and tooth splints	---

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Certificate History

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Date	Reference Number	Action
2022-08-09	3556898	First issue; Traceable to HD 60140582 0001 issued by NB0197
Current	3853816	Change to address of UK Responsible Person.

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