By Royal Charter

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 Global Regulatory & Quality

First Issued: **2022-08-09** Date: **2025-07-11** Expiry Date: **2029-05-26**

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Supplementary Information to UKCA 759368

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Number	Device Name	Intended purpose per IFU
Class IIb		
32854, 46647, 61669, 61670 and 66947	APTUS: For the wrist, hand, forearm, elbow, foot, ankle, knee and shoulder.	The fixation systems are intended for temporary fixation, correction, or stabilization of bones.
46638, 46642 and 47930	MODUS: For the mandible and mid-face.	The fixation and osteosynthesis systems are intended for use in oral and craniomaxillofacial surgery.
66699		CMX MODUS 2 Mandible plates are intended for the positionally and functionally stable fixation of fractures and osteotomies and for reconstructive procedures in craniomaxillofacial surgery of a specific patient.
Class IIa		
MD 0106 MD 0401	Instruments for fixation and osteosynthesis systems	---
MD 0402	Arch bars and tooth splints	---

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UKCA Certificate - Full Quality Assurance System Certificate History

Certificate No: **UKCA 759368**
Date: **2025-07-11**
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Date	Reference Number	Action
2022-08-09	3556898	First issue; Traceable to HD 60140582 0001 issued by NB0197
2023-07-26	3853816	Change to address of UK Responsible Person.
2024-04-05	30081275	Renewal. Administrative changes to device schedule for class IIb APTUS devices: GMDN codes 35685, 46646, 56642, 61573 and 61671 were removed. GMDN codes 32854 and 66947 were added. Administrative changes to device schedule for class IIb MODUS devices: GMDN codes 46646, 46647, 56642 and 61573 were removed. GMDN codes 46638 and 46642 were added. Addition of the in-house process for sterile packaging. Addition of critical subcontractor for the activity of "Manufacture".

Approved Body Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP, UK. Tel: + 44 845 080 9000
Corporate Contact: BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London, W4 4AL, UK.
A member of BSI Group of Companies.

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Date	Reference Number	Action
2024-09-05	30205273	Addition of subcontractor for manufacture of CMX M2 Orthognathics Positioning Aid. Addition of GMDN 66699 and Intended purpose per IFU. Addition of "knee" under the 'Device name' for 'APTUS'
Current	30470178	Addition of critical subcontractor for manufacture and crucial suppliers for surface treatment of screws and plates for fixation and osteosynthesis systems.

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