

# 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]

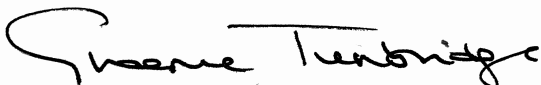
**No.** **UKCA 759368**  
**Issued To:** **Medartis AG**  
**Hochbergerstrasse 60E**  
**Basel**  
**4057**  
**Switzerland**

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: **2024-04-05**

Expiry Date: **2029-05-26**

...making excellence a habit.™

# UKCA Certificate - Full Quality Assurance System

## Supplementary Information to UKCA 759368

Issued To: **Medartis AG**  
**Hochbergerstrasse 60E**  
**Basel**  
**4057**  
**Switzerland**

Number	Device Name	Intended purpose per IFU
<b>Class IIb</b>		
32854, 46647, 61669, 61670 and 66947	APTUS: For the wrist, hand, forearm, elbow, foot, ankle, 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.
<b>Class IIa</b>		
MD 0106 MD 0401	Instruments for fixation and osteosynthesis systems	---
MD 0402	Arch bars and tooth splints	---

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

Date: **2024-04-05**

Expiry Date: **2029-05-26**

...making excellence a habit.™

# UKCA Certificate - Full Quality Assurance System

## Certificate History

Certificate No: **UKCA 759368**  
 Date: **2024-04-05**  
 Issued To: **Medartis AG**  
**Hochbergerstrasse 60E**  
**Basel**  
**4057**  
**Switzerland**

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.
Current	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".

...making excellence a habit.™