By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 642227**

Issued To: **Argon Medical Productions & Vertriebs GmbH & Co. KG**
Franz-Kirsten-Str.1
Bingen
55411
Germany

In respect of:

The design and manufacture of sterile dental implants, sterile and non-sterile abutments, prosthetic accessories and non-sterile drill bits and instrumentation connected to an active device.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2016-07-12** Date: **2021-05-07** Expiry Date: **2024-05-26**

...making excellence a habit.™

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 642227

Issued To:

Argon Medical Productions & Vertriebs GmbH & Co. KG
Franz-Kirsten-Str.1
Bingen
55411
Germany

Number	Device Name	Intended purpose per IFU
Class IIb		
MD 0403	K3Pro Rapid Implants	For placement in bone as a submucosal screw to which a prosthesis can be attached
MD 0403	K3Pro Sure Implants	For placement in bone as a submucosal screw to which a prosthesis can be attached
MD 0403	K3Pro Short Implants	For placement in bone as a submucosal screw to which a prosthesis can be attached
MD 0403	K3Pro C-Line Implants	For placement in bone as a submucosal screw to which a prosthesis can be attached
MD 0403	K3Pro R-Line Implants	For placement in bone as a submucosal screw to which a prosthesis can be attached
MD 0403	K3Pro S-Line Implants	For placement in bone as a submucosal screw to which a prosthesis can be attached
MD 0403	TA Healing abutments	Placed on the implants to support the superstructures
MD 0403	PA Temporary abutments	Placed on the implants to support the temporary supply
MD 0403	EAK preform abutments	Placed on the implants to support the superstructure
MD 0403	AA anatomic abutments	Placed on the implants to support the superstructure
MD 0403	FF-FreeForm abutments	Placed on the implants to support the superstructure

First Issued: **2016-07-12** Date: **2021-05-07** Expiry Date: **2024-05-26**

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 642227

Issued To:

Argon Medical Productions & Vertriebs GmbH & Co. KG
Franz-Kirsten-Str.1
Bingen
55411
Germany

Number	Device Name	Intended purpose per IFU
MD 0403	CCA/ UCLA abutments	Placed on the implants to support the superstructure
MD 0403	GAT Basis abutments	Placed on the implants to support the superstructure
MD 0403	KSA/Adhesive/scan abutments	Placed on the implants to support the temporary supply
MD 0403	CS-Cerec abutments	Placed on the implants to support the temporary supply
MD 0403	CAD-Premills abutments	Placed on the implants to support the superstructure
MD 0403	CG-Cloubase/Flexibase abutments	Placed on the implants to support the superstructure
MD 0403	EAZ-Emergenz abutments	Placed on the implants to support the superstructure
MD 0403	VBA-RapidFix abutments	Placed on the implants to support the superstructure
MD 0403	SBA-Bar Base abutments	Placed on the implants to support the superstructure
MD 0403	MB Multibase abutments	Placed on the implants to support the superstructure
MD 0403	FLA-Finder/locator abutments	Placed on the implants to support the superstructure
MD 0403	KKA-Ball top abutments	Placed on the implants to support the superstructure
MD 0403	KFO-orthodontic abutments	Placed on the implants to support the superstructure
MD 0403	RA rescue abutments	Placed on the implants to support the superstructure
MD 0403	DLA-Finder Pro abutments	placed on the implants to support the superstructure

First Issued: **2016-07-12** Date: **2021-05-07** Expiry Date: **2024-05-26**

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 642227

Issued To:

Argon Medical Productions & Vertriebs GmbH & Co. KG
Franz-Kirsten-Str.1
Bingen
55411
Germany

Number	Device Name	Intended purpose per IFU
Class IIa		
MD 0401	K3Pro Instruments	For placing and maintaining the components of the K3Pro dental implants
MD 0401	K3Pro Rapid Surgery Instruments	For placing and maintaining the components of the K3Pro dental implants

First Issued: **2016-07-12** Date: **2021-05-07** Expiry Date: **2024-05-26**

...making excellence a habit.™