



# EC CERTIFICATE

## Full Quality Assurance System

Certificate No.:10000434275-PA-NA-IND Rev. 0.0

Project No.: PRJC-500995-2014-MSL-IND

Valid Until: 27 May 2024

This is to certify that the quality system of:

### **Auxein Medical Private Limited**

**Plot No. 168-169-170, phase-IV, Kundli Industrial Area, HSIIDC, Sector-57, Sonapat, Haryana-131028, India.**

For design, production and final product inspection/testing of:

**Sterile Arthroscopy Devices – Knee System & Shoulder System**

Has been assessed with respect to:

**The conformity assessment procedure described in Annex II excluding section 4 of Council Directive 93/42/EEC on Medical Devices, as amended**

and found to comply

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:  
**Høvik, 24 May 2021**

For the issuing office:  
**Notified Body 2460  
DNV Product Assurance AS**



**Mariann Jeremiassen**  
Principal Assessor

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

NOTIFIED BODY 2460: DNV Product Assurance AS, Veritasveien 3, 1363 Høvik, Norway, Tel +47 67 57 88 00, [www.dnv.com](http://www.dnv.com)

ICP-4-5-11-MDD-f2, rev.0

## Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as “Forskrift om Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

## Certificate history:

Revision	Description	Issue Date
0.0	Original Certificate	2021-05-24

## Products covered by this Certificate:

Product Description	Product Name	Class
<b>Arthroscopy - Knee System</b>	<b>Auxilock GFS Ultimate (Mini &amp; Large)</b> <b>Titanium / UHMWPE</b> Width- 3.9 mm, Thickness: 1.55 mm Implant length: 12.0 mm & 16.5 mm Loop Length: Adjustable length <b>2 Variant with adjustable loop</b>	IIb
	<b>Auxilock GFS Mini</b> <b>Titanium / UHMWPE</b> Width 3.9 mm, Thickness: 1.55 mm Implant length: 12 mm Close Loop Length: 12.0 mm, 15 mm, 20 mm, 25 mm, 30mm, 35mm, 40 mm, 45 mm, 50 mm & 55 mm. Loop Length: Adjustable length <b>10 Variants with close loop</b>	IIb
	<b>Auxilock GFS II Large</b> <b>Titanium / UHMWPE</b> Width 4.42 mm, Thickness: 2.78 mm Implant length: 16.5 mm Close Loop Length: 12.0 mm, 15 mm, 20 mm, 25 mm, 30 mm, 35 mm, 40 mm, 45 mm, 50 mm & 55 mm. <b>10 Variants with close loop</b>	IIb

<b>Arthroscopy - Knee System</b>	<b>Auxilock Interference Screw Titanium</b> Diameter 7.0mm to 12.0 mm Implant length: Length 20 mm to 35 mm, in variation of 5 mm	IIb
	<b>Auxilock Interference Screw PEEK</b> Diameter 7.0 mm to 12.0 mm Implant length: Length 20 mm to 35 mm, in variation of 5 mm	IIb
<b>Arthroscopy – Shoulder System</b>	<b>Draw Tight with Anchor UHMWPE / PEEK</b> Dia. 1.8 mm & 3.2 mm Implant length: 4.9 mm & 6.8 mm Assembled product length 300.0 mm to 380.0 mm	IIb
<b>Arthroscopy – Shoulder System</b>	<b>Ti Screw-In Anchor (with and without needle) Titanium / UHMWPE</b> Dia. 2.8 mm to 6.5 mm Implant Length: 8.8 mm & 18.60 mm Assembled product length: 250.0 mm to 360.0 mm	IIb
<b>Arthroscopy – Shoulder System</b>	<b>PEEK Optima Screw-In Anchor PEEK / UHMWPE</b> Dia. 4.5mm, 5.5 mm & 6.5 mm Implant Length: 15.0 mm & 20.0 mm Assembled product length: 200.0 mm to 250.0 mm	IIb

The complete list of devices is filed with the Notified Body



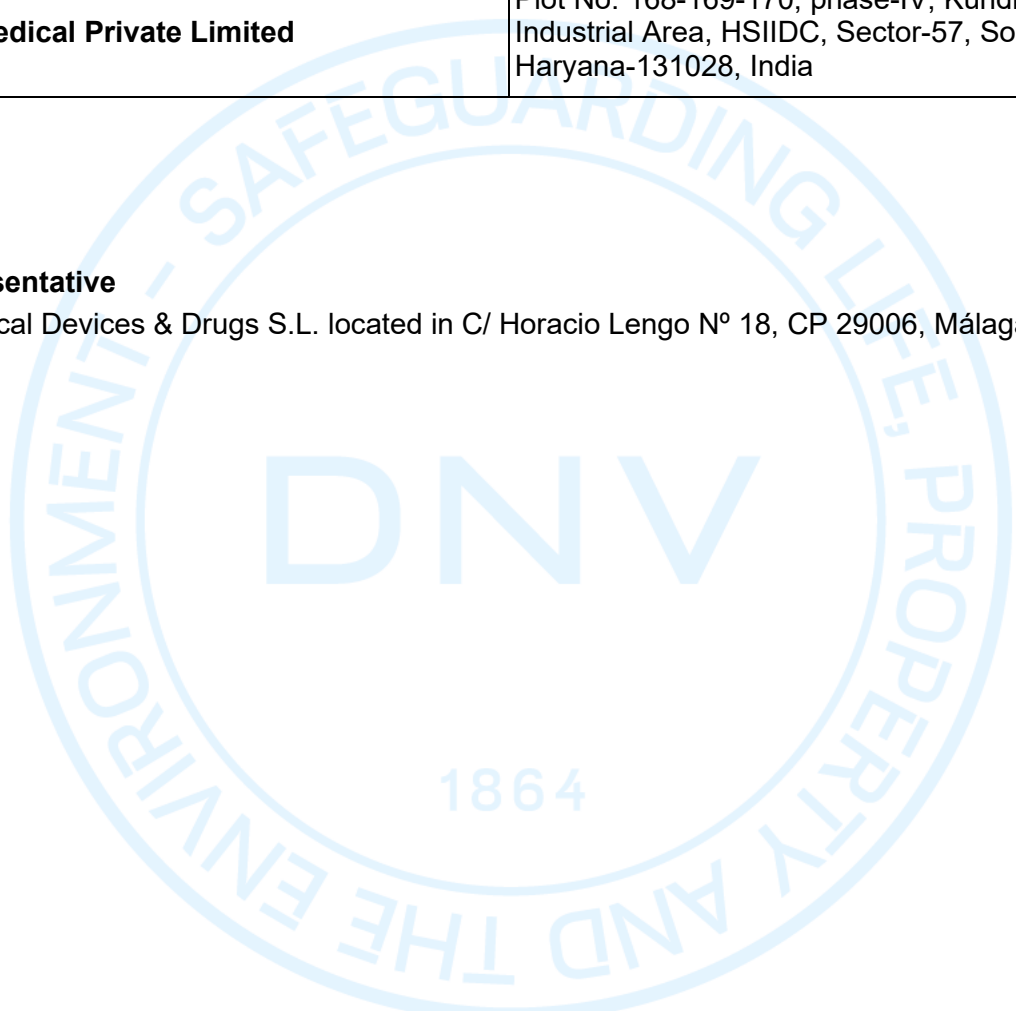
Certificate No.: 10000434275-PA-NA-IND Rev. 0.0  
Place and date: Høvik, 24 May 2021

### Sites covered by this certificate

Site Name	Address
<b>Auxein Medical Private Limited</b>	Plot No. 168-169-170, phase-IV, Kundli Industrial Area, HSIIDC, Sector-57, Sonapat Haryana-131028, India

### EU Representative

CMC Medical Devices & Drugs S.L. located in C/ Horacio Lengo Nº 18, CP 29006, Málaga, Spain.



## Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the Notified Body of any intended updating of the quality system and the Notified Body will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. the Notified Body reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

## Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number.

End of Certificate