

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, Sonepat, 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