

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Registration No.: HD 2060986-1

Manufacturer: Star Sports Medicine Co., Ltd.
Room A018, Floor 1, Building 1, NO.25, JingHai 2 Road, Beijing
Economic and Technological Development Zone,
100176 Beijing, P.R. China

Products: Metal Suture Anchors, Shaver Blades, Non-absorbable Surgical Sutures,
Suture Buttons, PEEK Suture Anchors, PEEK Interference Screw Systems,
Arthroscopic Shaver Systems, All-Suture Anchors, Meniscal Repair
Devices, Arthroscopic Access Cannulas and Spiked Ligament Staples

Replaces Approval, Registration No.: HD 60145514 0001

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II section 4 is required.

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TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.