



EC Certificate

EC Design-Examination Certificate

Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)
(Other devices than custom made or intended for clinical investigation)

No. I7 043036 0028 Rev. 01

Manufacturer:

WITTENSTEIN intens GmbH

Walter-Wittenstein-Strasse 1
97999 Igersheim
GERMANY

Product:

Implantable Telescope-Actuator Systems

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with AIMDD Annex 2 (4). This design of the devices conforms to the requirements of this Directive. For marketing of these devices an additional Annex 2 certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see:

www.tuvsud.com/ps-cert?q=cert:I7_043036_0028_Rev.01

Report no.:

713196369

Valid from:

2021-03-29

Valid until:

2024-05-26

Date,

2021-03-29

Christoph Dicks
Head of Certification/Notified Body



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Model(s): see below

Product: Implantable Telescope-Actuator Systems

Test Report No.: 71352750

Model:

FITBONE®
FITBONE®
FITBONE® TAA Instrument Set

Model No.:

TAA1160-T-225
TAA1180-F-245

Test Report No.: 713144437

Model:

FITBONE®
FITBONE®
FITBONE®
FITBONE®
FITBONE®
FITBONE® Screw Box
FITBONE® Receiver
FITBONE® Control Set
FITBONE® Retraction Control Set

Model No.:

TAA1140-F-205
TAA1160-F-225
TAA1140-T-205
TAA1180-T-245
TAA1380-F-245

Test Report No.: 713196369

Model:

FITBONE®
FITBONE®
FITBONE®
FITBONE®

Model No.:

TAA0940-F-200
TAA0940-T-200
TAA0960-F-220
TAA0960-T-220