NEWCLIP-TECHNICS

LETTER OF AUTHORIZATION

We, NEWCLIP TECHNICS located in PA de la Lande Saint Martin – 45 rue des Garottières - 44115 Haute-Goulaine – France, hereby authorize UAB OSTECA - Danės str. 47 – LT-92108 Klaipeda - Lithuania, to be our exclusive distributor for tenders on the Lithuanian market for the following products:

- Activmotion S
- Footmotion

Place, Date: Haute Goulaine, le 12/10/2023

Name / Function:
Jean-Pierre PODGORSKI/ General Manager

[redacted]

NEWCLIP TECHNICS SAS
Parc d'activités de la Lande Saint-Martin - 45 rue des Garottières
44115 HAUTE GOULAINE - France
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APE 4646Z - SIREN 441 810 603 RCS Nantes

Vertimas iš anglų kalbos

NEWCLIP TECHNICS

ĮGALIOJIMAS

Mes, NEWCLIP TECHNICS, esantys PA de la Lande Saint Martin – 45 rue des Garottieres – 44115 Haute-Goulaine – Prancūzija, šiuo raštu suteikiama UAB Osteca, esančią Danės g. 47, LT-92108 Klaipėda, Lietuva, išskirtines teises Lietuvoje platinti žemiau išvardintas produktų sistemas:

- Activmotion S
- Footmotion

Vieta, data: Haute Goulaine, 2023-10-12

Vardas / pareigos:

Jean-Pierre Podgorski / Generalinis direktorius

EC kokybės vadybos sistemos sertifikatas FR22/00000038

Vadybos sistema kompanijos

Newclip Technics S.A.S.

45 Rue des Garottieres, 44115 HAUTE-GOULAINE Prancūzija
SRN: FR-MF-000011809

buvo įvertinta ir sertifikuota kaip atitinkanti

MDR ES kokybės vadybos sistemos sertifikato (IX QMS Priedo)

reikalavimus toliau išvardintiems produktams
Registracijos apimtis nurodyta šio pažymėjimo antrame puslapyje

Šis sertifikatas galioja nuo 2023-07-07 iki 2027-09-14 ir lieka galioti, jei priežiūros auditai yra patenkinami.
Pakartotinis auditas turi būti atliktas ne vėliau kaip iki 2027-03-14
Leidimas Nr. 6. Sertifikuotas nuo 2022-09-14

EU Quality Management System Certificate FR22/00000038

The management system of

Newclip Technics S.A.S.

45 Rue des Garottières, 44115 HAUTE-GOULAINE FRANCE
SRN: FR-MF-000011809

has been assessed and certified as meeting the requirements of

MDR EU Quality Management System certificate (Annex IX QMS)

For the following products
The Scope of Registration appears on page 2 of this certificate

This certificate is valid from 07 July 2023 until 14 September 2027 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 14 March 2027.
Issue 6. Certified since 14 September 2022

Authorised by
Virginie Siloret
Global Medical Device Certification Manager

SGS Belgium NV NB 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 - www.sgs.com

Newclip Technics S.A.S.

MDR EU Quality Management System certificate (Annex IX QMS)

Class Is/m/r devices:
MDN 1208, MDS 1005, MDS 1010, MDS 1006: Instruments used in trauma and orthopaedic surgery. The Newclip Technics Class I Instruments are reusable transient invasive instruments or non-invasive devices either allowing the implantation and removal of trauma and orthopaedic devices. Some of them have a measuring function.
B-UDI : 3700569600328V, 3700569600338X, 3700569600318T, 3700569600348Z, 3700569600569B, 37005696003593, 3700569600579D, 3700569600108K, 3700569600589F, 3700569600128P, 3700569600599H, 3700569600218Q, 37005696003695, 37005696003797, 37005696003899, 3700569600399B, 3700569600408U, 37005696006092, 3700569600418W, 37005696004494

Class IIa devices:
MDN1208, MDS 1005, MDS 1010, MDS 1006
Sterile and non-sterile instruments for trauma and orthopaedic surgery: Instruments are transient or short-term invasive or non invasive devices either allowing the implantation and removal of trauma and orthopaedic devices or the cut of soft tissues. The devices are composed by sterile or non sterile single-use instruments or non sterile reusable instruments. Some of them are connected to an active device. Some of them have a measuring function.
B-UDI : 3700569600679G, 37005696004698, 37005696006296, 37005696005497, 3700569600479A, 3700569600508X, 3700569600659C, 3700569600518Z, 37005696004596, 3700569600669E, 37005696006194, 37005696006398, 3700569600428Y, 37005696004392, 37005696005395, 37005696005293

Class IIb devices (sold sterile and non sterile):
MDN 1102, EMDN P09120599
3700569600018J (B-UDI): Plates Alians Clavicle - Plates Alians Clavicle S – Intended purpose: Fixation of fractures, mal-unions, non-unions, and osteotomies of the clavicle in adults.
3700569600028L (B-UDI): Plates Alians Elbow – Intended purpose: Fixation of fractures and osteotomies of the distal humerus and proximal ulna in adults.
3700569600038N (B-UDI): Plates Alians Forearm – Intended purpose: Fixation of fractures and osteotomies of the radius and the ulna in adults.
3700569600048Q (B-UDI): Plates Alians Radius – Intended purpose: Fixation of extra-and intra-articular fractures as well as distal radius osteotomies in adults.
3700569600068U (B-UDI): Plates Activ Ankle – Intended purpose: Fixation of fractures, osteotomies and pseudarthroses of the distal and the diaphyseal fibula, the distal tibia and for the syndesmotic repair in adults.
37005696000992 (B-UDI): Plates Alians Proximal Humerus – Intended purpose: Osteosynthesis of fractures and fractures dislocations, osteotomies and non-unions of the proximal humerus in adults.
3700569600248W (B-UDI): Plates Activmotion - Activmotion S – Intended purpose: Knee osteotomy in adults.
3700569600118M (B-UDI): Plates PeriActiv – Intended purpose: Osteosynthesis of femoral periprosthetic fractures in adults.
3700569600138R (B-UDI): Plates Xpert Wrist – Intended purpose: Fixation of hand and forearm fractures, osteotomies and arthrodeses in adults.
3700569600158V (B-UDI): Plates Activmotion S DTO – Intended purpose: Bone reconstruction of the ankle joint in adults, including fixation of fractures and osteotomies of ankle, distal tibia and fibula.
3700569600168X (B-UDI): Plates Footmotion Plating System – Intended purpose: Arthrodeses, fractures and osteotomies fixation and revision surgeries of the foot in adults.
3700569600228S (B-UDI): Plates Activ Fuse – Intended purpose: Bone reconstruction of the ankle joint in adults including fractures fixation and arthrodeses of the ankle, distal tibia, talus, and calcaneus.

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MDN 1102, EMDN: P09120699
37005696002896 (B-UDI): Initial S - Intended purpose: Set of instruments or a set of instruments and implants (washers) to be used only in trauma or orthopaedic surgery, when Newclip Technics screws for osteosynthesis are fitted.

MDN 1102, EMDN: P09120601, P09120602
3700569600258Y (B-UDI): Screws associated to the plates Alians Proximal Humerus, Activmotion, Activmotion S and PeriActiv - Intended purpose: Fixation of osteosynthesis of upper and lower limb in adults.

MDN 1102, EMDN P09120599, P09120601, P09120602
3700569600208N (B-UDI): Initial C - Intended purpose: Fixation of fractures, mal-unions, non-unions, and osteotomies of the clavicle in adults.
3700569600178Z (B-UDI): Initial R - Intended purpose: Fixation of intra and extra-articular fractures as well as distal radius osteotomies in adults.
3700569600148T (B-UDI): Initial R Xpert - Intended purpose: Fixation of hand and forearm fractures, osteotomies and arthrodeses in adults.

MDN 1102, EMDN P09120599, P09120602, P09120603
37005696001995 (B-UDI): Initial F - Intended purpose: Arthrodeses, fractures and osteotomies fixation and revision surgeries of the foot in adults.

MDN 1102 EMDN: P09120601, P09120602, P09120603
37005696001893 (B-UDI): Screws associated to the plates Xpert Wrist, Initial R Xpert, Activmotion S DTO, Footmotion Plating System, Initial F - Intended purpose: Fixation of osteosynthesis of upper and lower limb in adults.

MDN1102 EMDN: P09120601, P09120602, P09120699
3700569600238U (B-UDI): Screws associated to the plates Activ Fuse - Intended purpose: Fixation of osteosynthesis of upper and lower limb in adults.

MDN 1102 EMDN: P09120599, P09120699, P09120601, P09120602
3700569600078W (B-UDI): Initial A - Intended purpose: Fixation of fractures, osteotomies and pseudarthroses of the distal and the diaphyseal fibula, the distal tibia and for the syndesmotic repair in adults.

MDN 1102 EMDN: P09120601, P09120602, P09120603, P09120699
3700569600088Y (B-UDI): Screws associated to the plates Alians Clavicle. Alians Elbow, Alians Forearm, Alians Radius, Activ Ankle, Initial R, Initial A, Alians Clavicle S, Initial C - Intended purpose: Fixation of osteosynthesis of upper and lower limb in adults.

MDN 1102 EMDN P09120601, P09120602, P09120603, P09120699
37005696002794 (B-UDI): Stand Alone Screws - Intended purpose: Fractures fixation, osteotomies and arthrodeses of bones.

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Conditions for & limitation to the validity of the certificate:
For placing on the market of Class III or class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors and Annex VIII rule 12 devices) covered by this certificate, a Technical Documentation Assessment Certificate according to Annex IX section 4 and 5 is required.

For Class I devices, audit done by SGS Belgium N.V. is limited to the specific aspect described in Article 52 section 7 of MDR (EU) 2017/745 (sterility, reusability or measurement function).

List of examinations and tests performed, which may include reference to relevant CS and harmonised standards, as per Annex XII, Chapter II, section 10 is available "on request" per email to NB1639@sgs.com.

Limitation:
N/A

Certification is based on following reports: - FR/MD/c236427 - CTC 1.4
Authorized representative name and address (if relevant): N/A
Previous certificate number: N/A
Change in between this certificate and previous one: change of scope for IIa class part