

ELEKTROTECHNICKÝ ZKUŠEBNÍ ÚSTAV



ELECTROTECHNICAL TESTING INSTITUTE - CZECH REPUBLIC
ELEKTROTECHNISCHE PRÜFANSTALT - TSCHÉCHISCHE REPUBLIK
INSTITUT ELECTROTECHNIQUE D'ESSAIS - RÉPUBLIQUE TCHÉQUE
ЭЛЕКТРОТЕХНИЧЕСКИЙ ИСПЫТАТЕЛЬНЫЙ ИНСТИТУТ - ЧЕШСКАЯ РЕСПУБЛИКА

Pod Lisem 129, 171 02 Praha 8 - Troja

EC CERTIFICATE FULL QUALITY ASSURANCE SYSTEM

issued in accordance with Annex 2 of Government Order No. 54/2015 Coll.
(Annex II of Directive 93/42/EEC)

No.: MED 150008

The Electrotechnical Testing Institute, Notified Body No. 1014, on the basis of the carried out audit results has decided that the quality system established at the

manufacturer

SARL C.H.O.C.
Rue Louis Lépine - Albasud 3, 82000 MONTAUBAN, France

for design, manufacturing and final inspection of medical device(s)

Implants for maxillo- and cranio-facial, dental and orthopaedic surgery - class IIb, models see enclosure No. 1

meets the provisions of Annex 2 of Government Order No. 54/2015 Coll., which specifies technical requirements for medical devices (Annex II of Directive 93/42/EEC). The certificate does not cover examination of the medical device design in accordance with Annex 2 clause 8 of Government Order No. 54/2015 Coll. (Annex II clause 4 of Directive 93/42/EEC).

The notified body agrees with attaching its identification number 1014 to CE marking, which will be affixed to the above mentioned medical device(s) in accordance with Article 6 of Government Order No. 54/2015 Coll. (clause 17 of Directive 93/42/EEC).

The decision was based on the results presented in the audit report No. **403340-01/03 of 08.01.2015**.

The approved quality system established at the manufacturer is subject to regular surveillance audits by the notified body in accordance with Annex 2 clause 11 of Government Order No. 54/2015 Coll. (Annex II clause 5 of Directive 93/42/EEC). The manufacturer must inform the notified body which approved the quality system about any intention of substantial changes to the quality system or the product range covered. In case that the conditions under which the certificate has been issued are violated, the notified body may suspend the validity of the certificate or cancel the certificate.

For class III medical devices this certificate can be used only with EC Design-Examination Certificate issued in accordance with Annex 2 clause 8 of Government Order 54/2015 Coll. (Annex II clause 4 of Directive 93/42/EEC).

Edition 1

The first issue of this Certificate from 27.01.2015 with validity until 27.11.2018

The validity of this Certificate is limited until: 27.11.2018

27.01.2015 change 29.08.2016

Prague

Mgr. Miroslav Sedláček
Head of Certification Body



Stamp



403340-01

Implant – Classe IIb

FOOT SURGERY – sterile

Product	Type / Model
Implant « MUST » (Peek Optima LT1)	38.86.30 : Implant MUST Ø3mm
	38.86.35 : Implant MUST Ø3.5mm
	38.86.40 : Implant MUST Ø4mm
	38.86.45 : Implant MUST Ø4.5mm

KNEE SURGERY – sterile

Product	Type / Model
Ligament cage (Peek Optima LT1)	38.86.01 : Ligament cage Ø12 lg 20mm
	38.86.02 : Ligament cage Ø12 lg 15mm
	38.86.03 : ligament screw
	38.86.04 : Ligament cage Ø12 lg 12mm
	38.86.05 : ligament screw
	38.86.06 : Ligament cage Ø12 lg 10mm
	38.86.07 : ligament screw

FOOT SURGERY – sterile / no sterile

Product	Type / Model
Micro- screw 4 « C »	38.93.12 : Micro-screw 4 « C » 12mm
	38.93.14 : Micro- screw 4 « C » 14mm
	38.93.16 : Micro- screw 4 « C » 16mm
	38.93.18 : Micro- screw 4 « C » 18mm
	38.93.20 : Micro- screw 4 « C » 20mm
	38.93.22 : Micro- screw 4 « C » 22mm
	38.93.24 : Micro- screw 4 « C » 24mm
	38.93.26 : Micro- screw 4 « C » 26mm

SHOULDER SURGERY – sterile

Product	Type / Model
EASY-FIX system (Peek Optima LT1)	38.86.09 : Easy-screw 30mm
	38.86.10 : Easy-screw 35mm
	38.86.11 : Easy-screw 40mm
	38.86.14 : Easy-screw 45mm
	38.86.12 : Easy-Lig inferior
	38.86.13 : Easy-Lig superior



FOOT SURGERY – sterile / no sterile

Product	Type / Model
Screw M.I.S.S. II	38.94.13 : screw MISS II 13mm
	38.94.15 : screw MISS II 15mm
	38.94.17 : screw MISS II 17mm
	38.94.19 : screw MISS II 19mm
	38.94.22 : screw MISS II 22mm

MAXILLO-FACIAL SURGERY – sterile

Product	Type / Model
Cathare screw Ø2mm	14.53.05/07/09/11/13/15/17/19/55/57
Cathare screw Ø1.3mm	38.83.01/02/03/10/12/14/16
Compression cross-shaped screws	14.45.05/07/09/10/11/12/13/14/55/57
Maxillo STD screws Ø2mm	14.51.05/07/09/11/13/15/17/19/55/57
Right plates	14.40.02/03/04/05/06/16/22/23/24/25/26
Unright plates	14.40.74/75/76/77/78/84/94/95/96/97/36/45/54/55/56/64/65/66/29
Paulus plates	14.38.04/06/08
Tridimensionals plates	14.39.06/10/12/15/18/27/80/81/82/83/85/86
ATM plates	14.20.01/02/03/04
LOG II plates	14.60.03/04/05/06/07/08

HAND AND FOOT SURGERY – SELF-BREAKING SCREWS – sterile

Product	Type / Model
Self-breaking screws Ø2mm	14.52.05/07/09/10/11/12/13/14/15/16/17/18/19/21/24
	MK145205/07/09/10/11/12/13/14/15/16/17/18/19/21/24 (secable STD)
	PL145205/07/09/10/11/12/13/14/15/16/17/18/19/21/24 (Vis PIN-UP)
	38.78.09/10/11/12/13/14/16/16/17
	14.43.05/07/09/11/13/15/21/25/27/29/43/45 (secable maxillo)
Cathare Self-breaking screws – MISS screws	38.52.13/15/17/19/22/20/24/26/28/30/32
	MK385213/15/17/19/22
	PL385213/15/17/19/22
Self-breaking screws	14.61.11/12/13/14
Self-breaking screws Ø1.3mm	38.82.09/10/11/12/13/14/15/16/18
	MK388209/10/11/12/13/14/15/16/18
	PL388209/10/11/12/13/14/15/16/18
Self-breaking screws Ø1.6mm	14.44.05/06/07/08/10/12/14
	14.57.05/08/09/10/11/12/14
	PL145705/08/09/10/11/12/14
	MK145705/08/09/10/11/12/14
SCARF Self-breaking screws	14.56.10/11/12/13/14/15/16/17/18/19/20/21/22/23/24/25/26/27/28
	MK145610/11/12/13/14/15/16/17/18/19/20/21/22/23/24/25/26/27/28 (secable SRD)
	PL145610/11/12/13/14/15/16/17/18/19/20/21/22/23/24/25/26/27/28
SCARF DF Self-breaking screws	38.56.10/12/14/16/18/20
	38.80.10/12/14/16/18/20
Arthrodesis Self-breaking screws	14.59.01/02/03/04/05/06/07/08/09/10/11

HAND AND FOOT SURGERY – PERFORATE SCREWS – sterile

Product	Type / Model
Perforate screws	38.49.10/12/14/16/18/20/22/24/26/28/30/32/34
PPDA screws	38.65. 10/12/14/16/18/20/22/24/26/28/30/32/34
	MK386510/12/14/16/18/20/22/24/26/28/30/32/34
	PL386510/12/14/16/18/20/22/24/26/28/30/32/34
4 « C » screws	38.68.02/03/04/05/06/07/08/09/10/11/12
	MK386802/03/04/05/06/07/08/09/10/11/12
	PL386802/03/04/05/06/07/08/09/10/11/12
Herbert screws	38.66.10/12/14/16/18/20/22/24/26/28/30/32/34/36/38/40/42
	MK386610/12/14/16/18/20/22/24/26/28/30/32/34/36/38/40/42
	PL386610/12/14/16/18/20/22/24/26/28/30/32/34/36/38/40/42
Acutrak screws	38.67.01/02/03/04/05/06/07/08
Shoulder screws	14.49.30/35/40
TIP screws	38.71.01/02/03/04/05/11/12/13/14/15/40/50
Dr Vernois screws	38.95.08/10/12/14/16/18/20/22
Condor Screw	38.87.10/12/14/16/18/20/22/24/26/28/30/32/34
MI-SCREW	38.92.30/32/34/36/38/40/42/44/46/48/50/52/54/56/58/60

ORTHOPEDIC SURGERY – PINS – sterile / no sterile

Product	Type / Model
Staple for Varisation	14.55.01/02/03/04
	MK145501/02/03/04
	PL145501/02/03/04
Pin with 1 or 2 tip, different diameters	14.63.01/02/05/06/07/08/09/10/11/31/32/34/35/36/37/38/39/40/41
	14.63.42/43/44/45
Pin cutting	14.63.02/33
Kapandji pin	14.63.12
Pin with ball	38.63.13/18 – 38.63.14/18 – 38.63.15/19 – 38.63.16/20 – 38.63.17/20
American cutting pins	BREF2522/3022/3522/4022/4522
Elastic pin	38.18.01/02/03/04/05/06/07/08/09/10/11/12/13/14
Binding tex	14.72.03/04/05/06
Binding tex	14.73.03/04/05/06 (maxillo-facial surgery)

ORTHOPEDIC SURGERY – EXTERNAL FIXING – sterile

Product	Type / Model
Chocafix	14.33.63/14.63.04/14.63.23
Umed-fix	14.33.64/14.63.21/14.63.22
Fixadyn	14.33.65/14.63.25/14.63.26

ORTHOPEDIC SURGERY – LIGAMENTOUS ANCHORAGE – sterile

Product	Type / Model
Ligamentous anchorage	14.48.01/02/03/04/05/06/07
Screw + disc	

ORTHOPEDIC SURGERY – SCREWS – sterile /no sterile

Product	Type / Model
Garden screw	38.85.01/02/03/04/05/06/07/08/09
Aline screw	SDIO1402400/1402401/81402402/1402403/1402405/1402407
SDRS polyaxial screws	SDIO1424809/SDIOINTRA
Vertebrae screws and hook / GPS (rachis)	
Endobutton plate	14.36.00 / 14.36.10
Albatros spongious screws	38.96.12/14/16/18/20/22/24/26/28/30/32/35/40
Albatros cortical screws	38.97.12/14/16/18/20/22/24/26/28/30/32/35/40
Albatros BMA0 plate	38.01.11R/38.01.14R/38.01.17R/38.01.11L/38.01.14L/38.01.17L
Albatros BMA plate	38.02.02R/38.02.03R/38.02.04R/38.02.05R/38.02.06R/ 38.02.02L/38.02.03L/38.02.04L/38.02.05L/38.02.06L
Albatros HMF plate	38.03.09R/38.03.13R/38.03.17R/38.03.21R/ 38.03.09L/38.03.13L/38.03.17L/38.03.21L
Albatros MTP plate	38.04.09R/38.04.12R/38.04.15R/38.04.18R/ 38.04.09L/38.04.12L/38.04.15L/38.04.18L
EAGLE screw Ø 4.6	38.98.20/22/24/26/28/30/32/34/36/38/40/42/44/46/48/50/52/54/56/58/60
EAGLE screw Ø 7	38.99.30A/35A/40A/45A/50A/55A/60A/65A/70A/75A/80A/85A/90A 38.99.55B/60B/65B/70B/75B/80B/85B/90B 38.99.70C/75C/80C/85C/90C

ORTHOPEDIC SURGERY – sterile

Product	Type / Model
Cerclage cable	46.74.01/02/03

FOOT SURGERY – sterile

Product	Type / Model
Memory staples – MEMOSTAP	PL101300/101315/101400/101416/101500/101517/101600/101618/101700/101719

IMPLANTOLOGY – sterile

Product	Type / Model
CIPS Implant	38.15.10
Exopost	38.15.01/38.15.02
Diasin	38.15.xx
Généric implants – CLG implants	38.15.xx
IHI Implants –SA Implants	SA.xxx / IHI.xxx



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