

ELEKTROTECHNICKÝ ZKUŠEBNÍ ÚSTAV



ELECTROTECHNICAL TESTING INSTITUTE - CZECH REPUBLIC
ELEKTROTECHNISCHE PRÜFANSTALT - TSCHIECHISCHE 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 080051

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 IIa, models se 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. **303045-01 of 07.07.2013, 403340-01 of 08.01.2015, 603763-01 of 17.05.2017.**

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 2

The first issue of this Certificate from 17.09.2008 with validity until 31.08.2013

The validity of this Certificate is limited until: 27.11.2018

29.08.2016 extended 17.05.2017

Prague


Mgr. Miroslav Sedláček
Head of Certification Body



Stamp



303045-01

Medical Devices – Class IIa

ORTHOPEDIC – no sterile

Product	Type / Model
Drills– Burrs for arthrodesis - trephine	14.37.30 : Drill Easy-Lig
	14.37.31 : Drill Easy-screw
	14.37.10 : Drill D7
	38.37.11/38.37.12/38.37.13/38.37.14/38.37.15/38.37.16/38.37.17/ 38.37.19: Burrs to ram
	14.37.05/14.37.06 : Burrs for arthrodesis
	38.33.57/38.33.58/38.33.59 : trephine
	14.37.32 : drill Albatros Ø2 lg 120
	14.37.33/14.37.34 : drill Eagle 4.6
	14.37.35/14.37.36 : drill Eagle 7
	14.37.20/28/21/22 : drill for canulated screws
	14.33.11/28/40/41/42/43/44/45/14.30.21/22 : AO screwdriver

IMPLANTOLOGY – no sterile

Product	Type / Model
Drills, burrs, ring, screws	PVG01/PPV : screw and screw holder
	P.FP.1 : positioning burr
	P.FP.5/P.FP.7/P.FP.08/09/10/11/12/13/14/15/16/17 : pointing drills
	P.F.ØLongueur : calibrator drills
	P.BD4500/4505/4510/4520/4530/4540 : peek rings Ø4.5
	P.BD500/505/510/520/530/540 : peek rings Ø5
	P.BD.6500/6505/6510/6520/6530/6540 : peek rings Ø6.5
	PBD50D/PBD65D : rings without cone
	PBL50/65 : rings without cone smooth
Accessory for dental implant (not stérile)	Pilar of healing and screw / false surb / transfert of imprint / analogue laboratory / o'ring / calcinable / healing screw Drill / key carries implant / tap / trefine

ORTHOPEDIC – PERCUTANEUS SURGERY – sterile

Product	Type / Model
Burrs for percutaneous surgery	38.37.01/02/03/04/05/06/07/08/09/20
SHAPED GUIDE M1 + CONICAL BURR 3.1	38.12.04

17.05.2017

End of the list



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