

ELEKTROTECHNICKÝ ZKUŠEBNÍ ÚSTAV



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

Pod lisem 129/2, 171 02 Praha 8 - Troja

EC DESIGN-EXAMINATION CERTIFICATE

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

No.: MED 200011

The Electrotechnical Testing Institute, Notified Body No. 1014, performed the design examination of medical device

**Synthetic resorbable material for bone regeneration PORESORB-TCP, class III
Granules from 0.16 mm to 6.0 mm**

in accordance with Annex 2 clause 8 of Government Order No. 54/2015 Coll., which specifies technical requirements for medical devices
(Annex II clause 4 of Directive 93/42/EEC) at

manufacturer **LASAK s.r.o.**
Českobrodská 1047/46, 190 01 Praha 9 - Hloubětín, Czech Republic

and states that the design of medical device meets the provisions of Government Order No. 54/2015 Coll. (Directive 93/42/EEC)

The details of the medical device design examination are presented in the audit report No. MED000008-04/02 of: 11.11.2019.

The manufacturer must inform the notified body about any intention of substantial changes to the approved design of medical device which could affect the conformity with essential requirements in accordance with Annex 1 of Government Order No. 54/2015 Coll. (Annex I of Directive 93/42/EEC). In that case 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.

Edition 1

The first issue of this certificate from 21.02.2020 with validity until 26.05.2024

The validity of this Certificate is limited until: 26.05.2024

17.06.2020

Prague

Mgr. Miroslav Sedláček
Head of Certification Body



MED000008-04

Certificate history

Date	Status	Reason
21.02.2020	Issuance	
17.06.2020	Change	Text correction

