



EA MLA Signatory
Český institut pro akreditaci, o.p.s.
Olšanská 54/3, 130 00 Praha 3

issues

according to section 16 of Act No. 22/1997 Coll., on technical requirements for products, as amended

CERTIFICATE OF ACCREDITATION

No. 328/2022

České vysoké učení technické v Praze
with registered office Jugoslávských partyzánů 1580/3, 160 00 Praha 6 - Dejvice, Company
Registration No. 68407700

to the Testing Laboratory No. **1379**
Mechanical Testing Laboratory

Scope of accreditation:

Testing of mechanical properties of ceramics (bending, fatigue), static, fatigue and wear tests of medical devices to the extent as specified in the appendix to this Certificate.

This Certificate of Accreditation is a proof of Accreditation issued on the basis of assessment of fulfillment of the accreditation criteria in accordance with

ČSN EN ISO/IEC 17025:2018

In its activities performed within the scope and for the period of validity of this Certificate, the Body is entitled to refer to this Certificate, provided that the accreditation is not suspended and the Body meets the specified accreditation requirements in accordance with the relevant regulations applicable to the activity of an accredited Conformity Assessment Body.

This Certificate of Accreditation replaces, to the full extent, Certificate No.: 224/2022 of 12. 5. 2022, or any administrative acts building upon it.

The Certificate of Accreditation is valid until: **25. 2. 2026**

Prague: 4. 7. 2022



Lukáš Burda
Director of the Department
of Testing and Calibration Laboratories
Czech Accreditation Institute
Public Service Company

**The appendix is an integral part of
Certificate of Accreditation No. 328/2022 of 04/07/2022**

Accredited entity according to ČSN EN ISO/IEC 17025:2018:

České vysoké učení technické v Praze
Mechanical Testing Laboratory
Technická 4, 160 00 Praha 6

Tests:

Ordinal number ¹	Test procedure/method name	Test procedure/method identification ²	Tested object
1	Determination of bending strength	ZP 01 (ASTM F382, p. 7.2.1; ISO 9585)	Bone plates
		ZP 02 (ČSN EN 843-1)	Ceramics
		ZP 03 (ČSN EN ISO 13356, p. 4.6; ISO 6474-1, p. 6.4.3; ISO 14704; ČSN EN ISO 6872, p. 7.3.1; ASTM C1161)	Ceramics
2	Determination of biaxial bending strength	ZP 04 (ČSN EN ISO 13356, p. 4.5; ISO 6474-1, p. 6.4.2; ASTM C1499)	Ceramics
3	Bending fatigue test	ZP 05 (ČSN EN ISO 13356, p. 4.10; ISO 6474-1, p. 6.9; ISO 22214)	Ceramics
		ZP 06 (ČSN EN ISO 14801)	Dental implants
		ZP 07 (ČSN EN ISO 11334-1, p. 5.6, 5.7)	Elbow crutch
		ZP 08 (ASTM F382, p. 7.2.2)	Bone plates
		ZP 09 (ASTM F1264, p. 6.3.1, 6.4.1, 6.5.1)	Intramedullary fixation devices
		ZP 10 (ISO 7206-4)	Femoral stem
		ZP 11 (ISO 7206-6)	Femoral neck
		ZP 12 (ČSN EN ISO 21536, p. 7.2.1; ISO 14879-1; ASTM F2083, p. 6.3.1; ASTM F1800)	Tibial tray

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Ordinal number ¹	Test procedure/method name	Test procedure/method identification ²	Tested object
4	Static test	ZP 13 (ISO 7206-10)	Femoral head
5	Wear test	ZP 14 (ČSN EN ISO 21536, p. 7.2.2; ISO 14243-2; ISO 14243-3)	Knee-joint prostheses

¹ asterisk at the ordinal number identifies the tests, which the Laboratory is qualified to carry out outside the permanent laboratory premises

² if the document identifying the test procedure is dated, only these specific procedures are used. If the document identifying the test procedure is not dated, the latest editions of the specified procedure are used (including any changes)

Explanatory notes:

ZP Testing method prepared by the Laboratory

