ELEKTROTECHNICKÝ ZKUŠEBNÍ ÚSTAV

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

Pod lisem 129/2, 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 210007

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 **Speciální Medicínská Technologie, s.r.o.**
Zbraslavská 1113, 252 42 Jesenice, Czech Republic

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

Cryosurgical device SMT – class IIa, for models see enclosure

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. **MED000102-04/01 of: 03.05.2021,**
MED000102-05/01 of: 12.02.2021.

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 05.05.2021 with validity until 26.05.2024
The validity of this Certificate is limited until: 26.05.2024

Digitally signed by Matei Andrei
Date: 2022.05.11 10:56:11 EEST
Reason: MoldSign Signature
Location: Moldova

elektrotechnický zkušební ústav ezú Pod lisem 129/2, 171 02 Praha 8 - Troja -1-

05.05.2021

Prague

Mgr. Miroslav Sedláček
Head of Certification Body

Stamp

CER/MED210007

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

Elektrotechnický zkušební ústav, s. p., Certification Body No. 3004 for certification of management systems, accredited by the Czech Accreditation Institute, o.p.s. in accordance with ČSN EN ISO/IEC 17021-1, grants the

CERTIFICATE

No.: 8220030

for the Quality Management System in accordance with

EN ISO 13485:2016

to the Firm

Speciální Medicínská Technologie, s.r.o.

Zbraslavská 1113, 252 42 Jesenice, Czech Republic

in localities: -

because it ascertained that the Quality Management System of the Firm in localities and processes:

Design, development, distribution and service of cryosurgical and electrosurgical medical devices and accessories, dental devices, tools and accessories

complies with all requirements of the above mentioned Standard documented by the Report No.: 220738-01 of: 22.04.2022

The validity of the Certificate is limited till: 24.04.2025

The Certified Organization is subject to annual check-ups carried out by the Certification Body. Any change within the organization concerning the certification shall be followed up and approved by the Electrotechnical Testing Institute. The validity of this Certificate may be suspended or cancelled in the event of non-compliance with the Standard on the basis of which the Certificate was issued.

Certification decision: 25.04.2022
Date of issue: 25.04.2022

Ing. Radek Teufl
Head of Certification Body

elektrotechnický zkušební ústav ezú Pod lisem 129/2, 171 02 Praha 8 - Troja -1-

Stamp

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220738-01

cryosurgery

SMT CS1

A handy devices designed for almost any cryosurgical treatment with liquid nitrogen. Cryosprays makes the LN2 treatment safe, easy and painless. All the instruments included are reusable. There are three models available in different volumes: 0.2l, 0.3l and 0.5l with spraying tips and practical stand included.
Cryosurgical sets are available, as a whole solution for treatment, LN2 storage, transport and spray refill.

ISO 13485:2016

CE 1014

General parameters

Freezing medium:	LN_2 (liquid nitrogen)
Working pressure:	90 kPa
Materials:	stainless steel body, vacuum insulation, plastic grip

	CS1	CS1/3	CS1-SM
Volume:	0.5l	0.3l	0.2l
Weight (empty):	470g	420g	350g
Dimensions D x h:	70mm x 300mm	70mm x 250mm	60mm x 200mm
Standard accessories:	SJ4, SJ6, SJ8, SJ10, ST6	SJ4, SJ6, SJ8,	SJ6

Jets and probes

Standard accessories contains stainless jets of different diameters (0.4mm to 1mm) and contact probe.

	D [mm]
SJ 4	0.4
SJ 6	0.6
SJ 8	0.8
SJ 10	1

	D [mm]
ST 6	6

Liquid nitrogen management

SMT offers whole solution for LN_2 storage, transport and cryospray refill, so the user can concentrate just on the treatment.

Several types of LN_2 containers of different volume are available (6l to 30l), supplied with a card.

An efficient withdrawal device UWD is safe, easy to operate device, that can fulfill the cryospray in few second.

A practical stand holds the spray, jets and probes together and ready.

All accessories is available separately or as a discounted set!

Speciální Medicínská Technologie, s.r.o.
Zbraslavská 1113, 252 42, Jesenice
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