

CE DECLARATION OF CONFORMITY

According to the sense of Art13of the Czech Act No. 22/1997

**SPECIALNI MEDICINSKA TECHNOLOGIE, s.r.o. /Special Medical Technology, Co. LTD/
IČO: 26179474
Papírenská 5, 160 00 Prague 6, Czech Republic**

Declares upon its excusive responsibility, that the medical product class IIa
(Rule 9 in Annex IX of 93/42/EEC)

Cryosurgical Unit SMT

which includes following types:

**Cryospray CS 1
Cryospray CS 1 E
Cryospray CS 1-SM
Cryospray CS 1/3
Cryospray CS 1/3 E**

meets essential requirements in Czech Government Order No. 54/2015 (Directive 93/42/ECC) and Czech Act No. 268/2014.

For the Declaration of Conformity was used Annex 2 of the Czech Government Order No. 54/2015 (Annex II of Directive 93/42/EEC).

The Declaration of Conformity was carried out in participation of the Notified Body No. 1014 – Electrotechnical Testing Institute (EZÚ).

Certificate No. MED 160032

The manufacturer claims that in the manufacturing process have not been used materials prohibited by Czech Government Order 481/2012 (Directive 2011/65/EU) and in that medical devices do not contain drug, animal tissue, human blood derivative or phthalates.

For the Declaration of Conformity was used these standards:

ISO 13485, IEC 62366, ISO 10993-1, ISO 15223-1, ISO 14971, ISO 17665-1

In Prague, April 19th, 2017

Sign:

Pavla Štrausová
(Managing Director)

Speciální Medicínská Technologie, s.r.o.
Papírenská 5
160 00 Praha 6
IČO: 26 17 94 74 (3)

Stamp: