



Notified Body 1023  
**INSTITUTE FOR TESTING AND CERTIFICATION, Inc.**,  
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

## EC Certificate - Production Quality Assurance No. 21 0207 QS/NB

The quality system of manufacturer

**SKALA-Medica s.r.o.**

**Gen. Janouška 886/42, 198 00 Praha 9, Czech Republic**

has been certified as meeting the requirements of

**Directive 93/42/EEC**

**on medical devices, Annex V**

for the following product category(ies):

**miniinvasive surgical atomizer**

The Notified Body No. 1023 declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subjected to periodical surveillance. For placing on the market of Class IIb and Class III devices covered by this certificate, an EC Type-Examination Certificate according to MDD Annex III is required.

**Valid from:** 2021-05-21

**Valid until:** 2024-05-27

**First Issued:** 2021-05-21

**Revision:** -



Date: 2021-05-21

Mgr. Jiří Heš  
Representative of the Notified Body No. 1023



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třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

**Annex to EC Certificate No. 21 0207 QS/NB**  
issued for manufacturer:

**SKALA-Medica s.r.o.**  
**Gen. Janouška 886/42, 198 00 Praha 9, Czech Republic**

**Product(s):**

**Name:** miniinvasive surgical atomizer

**Trade name(s):** MCR-4 TOPOL®

**Model(s):** -

**Class:** IIa

**GMDN:** 10226

**Facility(ies):**

SKALA-Medica s.r.o.

Gen. Janouška 886/42, 198 00 Praha 9, Czech Republic (seat)

SKALA-Medica s.r.o.

Wilsonova 222, 392 01 Soběslav, Czech Republic (manufacture)



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**Certificate History:**

Revision	Date	Reference Number	Action
	2021-05-21	803602892	Certification



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