



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

EC Certificate - Full Quality Assurance System No. 20 0126 QS/NB

The quality system of manufacturer

Flídr medical s.r.o.

Široký Důl 200, 572 01 Polička, Czech Republic

has been certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II excluding (4)

for the following product category(ies):

Medical supply units

The Notified Body No. 1023 declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subjected to periodical surveillance. For placing on the market of Class III devices covered by this certificate, an EC Design-Examination Certificate according to Annex II (Section 4) is required.

Valid from: 2021-03-23
Valid until: 2024-05-27
First Issued: 2020-03-24
Revision: a



Date: 2021-03-23

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



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Annex to EC Certificate No. 20 0126 QS/NB

issued for manufacturer:

Flídr medical s.r.o.
Široký Důl 200, 572 01 Polička, Czech Republic

Product(s):

Name: Ceiling arm
Trade name(s): -
Model(s): SR 50.01, SR 50.02, SR 50.11, SR 50.12, SR 50.21, SR 50.22, SR 51.11, SR 51.12, SR 51.21, SR 51.22
Class: IIb
GMDN: 35630

Facility(ies):

Flídr medical s.r.o. – head office
Široký Důl 200, 572 01 Polička, Czech Republic

Flídr medical s.r.o. – manufacturing site
Na Vyšehradě 1096, 572 01 Polička, Czech Republic



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Certificate History:

Revision	Date	Reference Number	Action
-	2020-03-24	803602833	Certification
a	2021-03-23	833600270	GMDN code update



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