

# EU Quality Management System Certificate No. 23 0493 QR/NB

Quality management system of the company

Flídr medical s.r.o.

Široký Důl 200, 572 01 Polička, Czech Republic

SRN: SRN: CZ-MF-000012476

is certified in accordance with the requirements of

## REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on medical devices, Annex IX, Chapters I and III

for the following device-range:

### Medical supply units

Notified Body No. 1023 declares that it has assessed the quality management system of the above manufacturer in accordance with Annex IX, Chapters I and III of Regulation (EU) 2017/745. The quality management system put in place by the manufacturer for the design, manufacture and final inspection of the products concerned complies with the requirements of Regulation (EU) 2017/745 and is subject to regular surveillance audits. In the case of Class IIb implantable devices as referred to in Article 52, paragraph 4, second subparagraph, which are covered by this EU Certificate, a complementary EU Technical Documentation Assessment Certificate is required in accordance with Annex IX, Chapter II. A detailed description of the system elements, requirements and measures adopted by the manufacturer is provided in the final report No 803602910, which is issued together with the present certificate.

Valid from: 2023-10-31 Valid until: 2028-10-31

Previous EU certificate No.: Previous EU certificate issue date: -

Date of issue: 2023-10-31

Mgr. Jiří Heš Representative of Notified Body No. 1023



## Annex to EU Quality Management System Certificate No. 23 0493 QR/NB

issued to the manufacturer:

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

#### Manufacturer details:

Manufacturer's company name: Flídr medical s.r.o.

Single registration number (SRN): CZ-MF-000012476

Registered office address: Široký Důl 200, 572 01 Polička,

Czech Republic

Production site address: Na Vyšehradě 1096, 572 01 Polička,

Czech Republic

### <u>Details of the authorised representative (if required):</u>

Name of the EU authorised representative: -

Address of the EU authorised representative: -

Date of issue: 2023-10-31

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Mgr. Jiří Heš Representative of Notified Body No. 1023



## Annex to EU Quality Management System Certificate No. 23 0493 QR/NB

issued to the manufacturer:

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

#### Product(s):

Product name: Terminal units for compressed medical gases

and vacuum

Trade mark(s): -

Model(s): R14

Class:

Intended Use: Used for supply and outlet gas media in specialized areas

of medical devices.

Product name: Wall platforms

Trade mark(s): -

Date of issue: 2023-10-31

Model(s): R14

Class: NR-H I, NR-H II, NR-S

**Intended Use:** Used for supply and outlet gas and electric media.

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Mgr. Jiří Heš

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## Annex to EU Quality Management System Certificate No. 23 0493 QR/NB

issued to the manufacturer:

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

Product name: Ceiling bridge-solid

Trade mark(s):

Model(s): SM-P 5.2, SM-P 5.4

Class:

**Intended Use:** Used for supply and outlet gas and electric media.

Product name: Ceiling bridge-lifting

Trade mark(s):

Model(s): SM-Z 5.2, SM-Z 5.4

Class:

Date of issue: 2023-10-31

Intended Use: Used for supply and outlet gas and electric media.

NOTIFIED BODY 1023

Mgr. Jiří Heš

Representative of Notified Body No. 1023



## Annex to EU Quality Management System Certificate No. 23 0493 QR/NB

issued to the manufacturer:

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

Product name:

Wall platform-universal

Trade mark(s):

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Model(s):

NR-U 1, NR-U 2, NR-U 3

Class:

Ilb

**Intended Use:** 

Used for supply and outlet gas and electric media.

Product name:

Ceiling arm

Trade mark(s):

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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:

llb

**Intended Use:** 

Used for the transmission of gas and electrical media in

the workspace in the rooms of medical equipment and

other special operations.



Date of issue: 2023-10-31

Mgr. Jiří Heš

Representative of Notified Body No. 1023

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