

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 800408 R000

Manufacturer: Fuhrmann Medical s.r.o

Address:

Komenského 404

Habartov

CZ-357 09

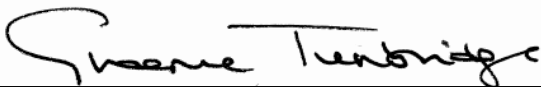
Czech Republic

Single Registration Number: CZ-PR-000003742

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):



Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2024-07-10**

Current Issue Date: **2024-07-10**

Starting Validity Date: **2024-07-10**

Expiry Date: **2029-07-09**

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Device Schedule: Article 22.3 Systems and Procedure Packs

Device(s)	Highest Risk Classification within the System or Procedure Pack
Obstetrical/Gynaecological Procedure Packs	Class Is
Disinfection Procedure Packs	Class IIa
Anaesthesia Procedure Packs	Class IIa

For Systems and Procedure Packs under Article 22.3, the Notified Body conformity assessment is limited to the aspects relating to ensuring sterility until the sterile packaging is opened or damaged.



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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	30049748	Issued



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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.