EU Declaration of Conformity

Manufactured by: EMEDIS s.r.o., 17. listopadu 170, 549 41 Červený Kostelec
SRN: CZ-MF-000035667

declares that the EU Declaration of Conformity is issued under the sole responsibility of the manufacturer Pro-Charitu s.r.o. and that the in vitro diagnostic medical device listed below:

HistoFor BFS

Basic UDI-DI 8596146HISTOFOR01RT
Type: see the annex to this document

complies with European Union legal regulations:

Regulation (EU) 2017/746 of the European Parliament and of the Council on in vitro diagnostic medical devices, Act No. 22/1997 Coll., on technical requirements for products, and on amendments and additions to certain acts, Act No. 375/2022 Coll., on medical devices and in vitro diagnostic medical devices.

The manufacturer has demonstrated the conformity of the product by issuing this Declaration of Conformity based on the technical documentation drawn up in accordance with Annex II and III of EU Regulation 2017/746.

Categorisation: In vitro diagnostic medical device; abbreviated IVD

Classification: **class** A, according to Annex VIII, Rule 5 of EU Regulation 2017/746

Specified intended use: HistoFor BFS is designed for fixation and transport of biological material

The product is safe for its intended purpose under normal use. It is functionally fit for its intended use. The manufacturer is responsible for the quality that is in accordance with the technical documentation and the essential requirements for the product.

Harmonised standards:
ČSN EN ISO 13485:2016 Medical devices – Quality management systems – Requirements for the purposes of the regulation
ČSN EN ISO 14971:2020 Medical devices – Application of risk management to medical devices
ČSN EN ISO 15223-1:2022 Marks for labels, marking and information provided along with medical devices – Part 1: General requirements
ČSN EN 13612:2002 Functional evaluation of in vitro diagnostic medical devices
ČSN EN 14254:2004 Disposable containers for the collection of samples of human origin other than blood
ČSN EN ISO 18113-1:2012 In vitro diagnostic medical devices – Information provided by the manufacturer (labelling) – Part 1: Terms, definitions and general requirements
ČSN EN ISO 18113-2:2012 In vitro diagnostic medical devices – Information provided by the manufacturer (labelling) – Part 2: In vitro diagnostic agents for professional use

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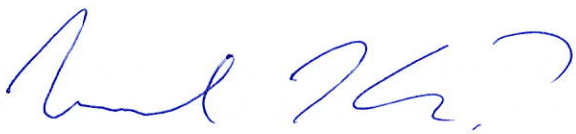
Annex:

REF	Name
120020	HistoFor BFS-20
120005	HistoFor BFS-40
120006	HistoFor BFS-60
120007	HistoFor BFS-125
120008	HistoFor BFS-180
120016	HistoFor BFS-250
120017	HistoFor BFS-500
120018	HistoFor BFS-1000
120019	HistoFor BFS-2500
120022	HistoFor BFS-5000
120001	HistoFor BFS-L1
120002	HistoFor BFS-L5
120003	HistoFor BFS-L10
120021	HistoFor BFS-L20

Any and all unauthorised changes to this declaration will render the declaration invalid.

Name: MVDr. Michal Krejčí
Function: Managing Director
Date: 1 May 2024
Signed by:



www.histofor.cz www.emedis.cz
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