Certificate of CE-Registration

This is to certify that, in accordance with the Medical Device Directive 93/42/EEC, MDSS GmbH agrees to perform all duties and responsibilities as the Authorized Representative for:

Micromedics, Inc.
1270 Eagan Industrial Road, Suite 120 St. Paul,
Eagan, MN 55121
USA

as stipulated and demanded by the aforementioned Directive. The German Competent Authority has allocated the medical devices of the Manufacturer registration numbers as foreseen in:

Annex A dated May 07, 2025

The Manufacturer has provided MDSS with the appropriate Declaration(s) of Conformity confirming that the medical devices fulfill the applicable requirements of Directive 93/42/EEC.

The devices are covered by this Certificate as long as MDR 2017/745 Article 120 (3) applies to them. The applicability is evaluated by and under responsibility of the Manufacturer. MDSS has to be informed once that Article is no longer applicable.

In addition, the applicability may be supported by evidence documents in accordance with the “Q&A on practical aspects related to the implementation of Regulation (EU) 2023/607”. Devices for which the Notified Body (NB) Certificate(s) show(s) an end of period in the past are only covered by this Certificate if they are covered also by evidence documents referenced in attached Annex A.

This Certificate is valid without signature and can be traced within MDSS’ electronic system.

Certificate No.: 875927

Annex A dated May 07, 2025
Manufacturer: Micromedics, Inc.

Evidence documents regarding applicability of MDR Art. 120 (3): Manufacturer Declaration (signed on): *Manfacturer Declaration 29APR2025 (29 APR 2025)* NB Confirmation Letter (signed on): *Reference: 291657 (23 January 2025)*						
UMDNS Code Description Notified Medical Device Product Name & Catalogue Number	**UMDNS Code**	**Risk Class**	**Cat. Code**	**Registration Number**	**NB No. / NB Certificate No.**	**NB Cert. Valid Until YYYY-MM-DD**
Applicator, Other	**15-689**	**IIa**	**10**	**DE/CA09/00025533**	**0297/291657MR2**	**2024-01-29**
Lap Spray - Applicators/Spray Sets; Biomaterial Applicators and Tips						
Devices as listed on the DoC: *"DoC Lap Spray" signed on 26 April 2021* Devices as listed on the DoC: *"90147 DoC" signed on 22 NOV 2024*						
Regulators	**13-320**	**II a**	**04**	**DE/CA09/00062244**	**0297/291657MR2**	**2024-01-29**
Regulators						
Devices as listed on the DoC: *"Regulators - DoC 91146 2023" signed on 02 November 2020*						
Syringe, Other	**15-256**	**II a**	**10**	**DE/CA09/00102545**	**0297/291657MR2**	**2024-01-29**
Graft Delivery Device						
Devices as listed on the DoC: *"DoC MDD Graft Delivery" signed on 30 January 2019*						
Canulae	**10-561**	**II a**	**10**	**DE/CA09/00109647**	**0297/291657MR2**	**2024-01-29**
Endoscopic Applicator						
Devices as listed on the DoC: *"DoC 90890 Endoscopic Applicators" signed on 26 October 2020*						