General Medical Italia LTD Swiss Branch
Piazzetta Luigi Fontana 4,
6850 Mendrisio,
Switzerland

EC-certification application nr. MDR-2028-1 dated 2023-10-27

Subject	Certification of quality system and product range, based on Medical Device Regulation (EU) 2017/745 concerning medical devices, Annex IX Chapters I, III and TDA in Section 4.
Manufacturer	General Medical Italia LTD Swiss Branch Piazzetta Luigi Fontana 4, 6850 Mendrisio, Switzerland SRN: CH-MF-000030023
Decision	A certificate will be issued for the manufacturer. The details of the certified addresses, activities, devices and their intended purposes covered, risk classifications, standards and common specifications followed as well as applicable test and audit reports referred to, are listed in the Attachment 1 of the certificate.
Justification	SGS Fimko Ltd has assessed manufacturer's quality management system. Quality management system meet the requirements of Annex IX of Medical Device Regulation (EU) 2017/745. The decision is based on audit report GMI_V1-S2_FPMDREG3019 - MD Audit Report Ver E 20231228, TDA report GMI - FPMDREG3020 - MDR Technical Documentation Assessment Report Ver E 20231228 and recommendation on 2023-12-28. The manufacturer has signed the undertaking to follow the obligations of Annex IX of the Regulation.
Certificate related to decision	FI24/0000001 Issue 1
Valid until	This decision is valid until 09 January 2029 providing the requirements of the certification are fulfilled.
Date	Helsinki, 10 January 2024

Seppo Vahasalo, NB Manager
SGS Fimko Ltd, Notified Body 0598

If you disagree with a SGS decision, you have the possibility to appeal. Please either request our GS0601FI Appeals form or email to nbmed.fimko@sgs.com with **Subject: Appeal to decision** your request with all information that support your appeal that the decision should be changed. Possible unsolved dispute can be appealed to Helsinki Administrative Court.