FI26/08258P0 14 July 2026

Guangzhou Yikang Medical
Equipment Industrial Co., Ltd.
Room 101, No. 69, Huangge Section, Shinan Road, Nansha District, Guangzhou, 511455,
Guangdong Province, P.R.China

EC-certification agreement MDR-2035-3 dated 2025-07-30

Subject	Certification of quality system and product range, based on Medical Device Regulation (EU) 2017/745 concerning medical devices, Annex IX Chapters I and III.
Manufacturer	Guangzhou Yikang Medical Equipment Industrial Co., Ltd. Room 101, No. 69, Huangge Section, Shinan Road, Nansha District, Guangzhou, 511455, Guangdong Province, P.R.China SRN: CN-MF-000031955
Decision	FI26/08258P0: A certificate will be issued for the manufacturer adding new models and devices: - new model A3-2 for Basic UDI-DI: 697534359A3MRA - new Basic UDI-DI: 697534359A1miniX8 with conditions or limitations - new Basic UDI-DI: 697534359A8miniZM, 697534359SL4IRA, and 697534359A6MRK to the extended scope of rehabilitative gymnastics and physiotherapy equipment. The details of the certified addresses, codes, 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 MDR-2035_Guangzhou Yikang_2025ES_FPMDREG3019 - MD Audit Report Ver H Rev.1 2026-05-28 combined with Technical documentation assessment reports: MDR-2035_2025ES_Gait training_FPMDREG3020 - MDR Technical Documentation Assessment Report Ver H Rev.2 2026-06-15 and MDR-2035_2025ES_A1min_FPMDREG3020 - MDR Technical Documentation Assessment Report Ver H Rev.1 2026-05-28 and recommendations therein on 2026-06-15 and 2026-05-28. The manufacturer has signed the undertaking to follow the obligations of Annex IX of the Regulation.
Certificate related to decision	FI25/1008008 Issue 4
Validity	This decision is valid from 14 July 2026 until 23 January 2030 providing the requirements of the certification are fulfilled.
Date	Helsinki, 14 July 2026

Jani Högman, Certifier
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.