ECM EUROPE

Your partner for life

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Subject: extended validity of MDD CE certificate of ECM MTS products until Dec. 31, 2028 as per Regulation (EU) 2023/607

To whom it may concern:

This is concerning the Medical Device Regulation (EU) 2017/745 and the MDR amendment as per Regulation (EU) 2023/607 which allows for the extended acceptance of current MDD CE certificates.

The ECM Europe Quality Management System meets the requirements of the standard EN ISO 13485:2016+A11:2021 and ensures compliance with MDD 93/42/EEC and MDR (EU) 2017-745.

With regards to its medical devices, the ECM Europe CE Certificate issued by Dekra Certification, in accordance with Directives 93/42/EEC, will remain valid after the end of the period indicated on the certificate until 31 December 2028.

- ***With the limitation: No changes in the design and intended purpose!***

ECM Europe and Dekra Certification have a written agreement in place for the conformity assessment for MDR certification in respect of the medical devices covered by the CE certificate number 2144240CE01. Furthermore ECM Europe will continue to meet the requirements of MDD 93/42/EEC, MDR (EU) 2017/745 and Regulation (EU) 2023/607.

ECM will continue supplying its medical devices in compliance with CE regulations, today and in the future. The current CE Certificate will be replaced by the CE certificate according to MDR (EU) 2017/745, after approval by our notified body. ECM will inform you promptly once this has been achieved.

Sincerely,

ECM Europe BV
Maarten Kanters
QARA manager
Signature