EC CERTIFICATION

QUALITY MANAGEMENT SYSTEM CERTIFICATE

Regulation (EU) 2017/745 for Medical Devices, Annex IX Chapters I & III

We hereby declare that a conformity assessment based on a quality management system and technical documentation has been carried out following the requirements of Regulation (EU) 2017/745 for Medical Devices.

We certify that the documentation conforms to the relevant provisions of the aforementioned regulation, and the result entitles the organization to use the CE 2862 marking on the products listed below.

Certificate Number:
28620166342

Revision:
00

Initial Certification Date:
24 January 2024

Certificate Decision Date:
24 January 2024

Certificate Issue Date:
24 January 2024

Certificate Expiry Date:
13 September 2028

TyTek Medical Inc

8904 Beckett Rd., West Chester, OH 45069 USA

Manufacturer SRN: US-MF-000032794

Authorised Representative Name
Emergo Europe B.V.
Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands

Scope:

Sterile chest decompression needles

Mikael Hagelin
Certification Authority, MDR
Intertek Medical Notified Body AB,
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Intertek Medical Notified Body AB is a Notified Body in accordance with the requirements set out in EU Regulation 2017/745 on medical devices, with the identification number 2862.

State of Ohio , County of Butler, I, Donna Kramer,
have acknowledged this document in front of a Notary
Public on January 29, 2024