

# 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.

## 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

**Certificate Number:**

28620166342

**Revision:**

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**Initial Certification Date:**

24 January 2024

**Certificate Decision Date:**

24 January 2024

**Certificate Issue Date:**

24 January 2024

**Certificate Expiry Date:**

13 September 2028



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Mikael Hagelin  
Certification Authority, MDR  
Intertek Medical Notified Body AB,  
Torshamnsgatan 43,  
Box 1103, SE-164 22 Kista, Sweden

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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.

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