

Declaration of Conformity

Regulation (EU) 2017/745

Manufacturer: Ferno Aviation and Military Systems

Manufacturers' address: 735 Branch Drive Alpharetta, GA 30004, USA

Unique registration number: (available when the managing system will be implemented by the
(Art. 31(2)) European Commission)

EU Authorized representative: Ferno S.r.l., Via B. Zallone 26, 40066, Pieve di Cento (BO),
Italy

The manufacturer declares under its own responsibility that the medical device(s):

Name of device(s): Hamilton T1 Surface Mount

Product(s) Code: FA858A001

Class of device(s): I
(Annex VIII)

Annex applied for the CE marking: Annex II and Annex III

Intended use: Mounting Hamilton T1 Ventilator

Base UDI-DI: (available when the managing system will be implemented by the
(Art. 29(1)) European Commission)

In accordance with the provisions of harmonized and non-harmonized standards:
EN 1789:2007+A2:2014 paragraphs 4.5.9 and 5.4 (CEN 1789)
SAE J3043, SAE J2917, SAE J2956, SAE J3044

Complies with the essential requirements listed in Annex I of the European Regulation 2017/745 concerning medical devices

Ferno Aviation and Military Systems maintains' a Quality Management System that fulfills the requirements of ISO 13485:2016.

06/07/2021
Date (m/d/y)

Andrew Stavres - Quality Manager
Name and Title


Signature

This document is compiled in accordance with Annex IV-EU Declaration of Conformity

United States/Ferno Aviation and Military Svstems/ 735 Branch Drive Alpharetta, GA 30004

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