FERNO

FERNO S.R.L. *n. RI BO/C.F./P.IVA 01693660977 capitale sociale € 53.712,00 Società Unipersonale*

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Via B. Zallone 26 – 40066 Pieve di Cento (BO) ITA ***www.ferno.it***

EN 1789:2020

Declaration of Compliance

To whom it may concern,

Here, Ferno S.r.l., declare that the medical device:

STBC - Bio-containment system for ambulance transport

with **REF** Number: **21-00008** and

Test(s) performed: from 29/06/2021 to 30/06/2021

has satisfied all requirements of paragraph(s) 4.4.11 and 5.3 of EN 1789:2020 (including Amendment +A2 1789:2014 4.5.9 and 5.4) in order to achieve CEN compliance for Dynamic testing. Appropriate tests have been performed by the Ferno S.r.l and witnessed by a third party (TÜV Italia SRL – PS-Laboratory Division) and the specification of the medical device tested has been documented.

All current amendments (EN 1789:2007 +A2 1789:2014) available at the time of issue are included.

COMPANY REPRESENTATIVE: Katarzyna Zofia Chrusciel **SIGNATURE** Katarzyna Chrusciel

TITLE: EU Compliance Manager (PRRC) **DATE:** 2021-03-10

PLACE: Pieve di Cento (BO), Italy

Italia

TEST REPORT

CITY CRASH TEST ON BIOCONTAINMENT SYSTEM ACCORDING TO EN 1789:2021

Customer *(Richiedente):*

- Dept./Firm *(Ente/Società):* FERNO S.r.l
- Mr./Mrs *(Sig./Sig.ra.):* Marco TASSINARI
- Address *(Indirizzo):* Via B. Zallone 26, I-40066 Pieve di Cento (BO)

Test Request Form no.: *Modulo Richiesta Prova n.:* MES1739700A00TR	Test Report sent to: *Rapporto inviato a:* Mr. Marco TASSINARI
Name and Signature of the test engineer: *Nome e Firma esecutore prova:* Simone Ferro	Name and Signature of the Technical reviewer: *Nome e Firma del Revisore tecnico:* Andrea Rotundo
Date of test samples receipt: *Data ricevimento campioni:* -	Date of test execution: *Data esecuzione prove:* From 29/06/2021 to 30/06/2021
Site of test execution: *Località esecuzione prove:* ☐ Via Brandizzo 123 I-10088 Volpiano TO Italy ☒ Via Benedetto Zallone, 26, 40066 Pieve di Cento BO	Witness to the test: *Presenti alle prove:* Marco Tassinari

The test results contained in this Test report relate to the tested samples only as received.
I risultati del presente rapporto di prova si riferiscono esclusivamente al campione sottoposto a prova così come ricevuto.

The integral reproduction of the present Test report is allowed; the partial reproduction must be authorized in writing by the Lab.
E' ammessa la riproduzione integrale del presente Rapporto di prova da parte del Richiedente; la riproduzione parziale dev'essere autorizzata per iscritto dal Laboratorio.

I dati forniti dal cliente di cui il laboratorio declina la responsabilità verranno identificati con carattere sottolineato.
The data provided by the customer for which the laboratory declines the responsibility will be identified with an underlined character

Italia

Object: Speed letter for status of project

Product Service Division

Product: Device for transporting patients with infectious diseases.
Prodotto:

Customer: FERNO S.r.l
Client:

Trademarks: FERNO S.r.l
Marchio commerciale:

Project: MES1739700A00TR
Progetto:

Quotation n°: 0722263885
Offerta n°:

Models: - 21-00008 BIOCONTAINMENT SYSTEM
Modelli:

Standards: - EN 1789:2021
Norma:

Dear Customer,
Here following we confirm that the tests shown in the offer have been performed and concluded with positive results.
At your disposal for any question.
Best regards.

TÜV Italia S.r.l.

Project Handler: Simone FERRO