DECLARATION OF CONFORMITY

Manufacturer: Timpel S.A.
Rua José Leonardi, N 280, Bloco A, Aeroporto - Pato Branco, Paraná, 85.503-000, Brasil.

Authorized EU-representative: MDSS GmbH
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30175 Hannover, Germany
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Notified Body BSI Group The Netherlands B.V.
Say Building, John M. Keynesplein 9, 1066 EP
Amsterdam - Netherlands
Notified Body number: 2797

CE 2797

EC Certificate Number: CE 708385

We hereby declare under our sole responsibility that the medical device:

Product:	**THORACIC ELECTRICAL IMPEDANCE TOMOGRAPHY SYSTEM** • ENLIGHT 2100 (TPL-E2100-0)
Applicable Standards	EN ISO 13485:2016 / AC:2016 EN ISO 14971:2012 EN 60601-1:2006 / AC:2010 / A1:2013 EN 60601-1-2:2015 EN 60601-1-6:2010 EN 60601-1-8:2007 / AC:2010 EN 62366:2008 EN ISO 10993-1:2009 / AC:2010 EN ISO 15223-1:2016 EN 1041:2008 EN 62304:2006/AC:2008 EN ISO 14155:2011 MDD 93/42/EEC:2007
Class and rule:	Class IIA – Rule 10
Technical file document:	Technical File Index – TF.210.01B_EN
Conformity assessment procedure:	The conformity procedure followed is in accordance with **Annex II excl. section 4** of the Medical Device Directive 93/42/EEC.
Others:	Equipment and its accessories do not contain raw material from animal origin, hemoderived or administrate/contains medicine; • Its components are biocompatible and do not offer hazardous toxicity or flammability to users; • Meets all the provisions of the directive 93/42/EEC which apply to it.

This declaration is valid until the release of a new Technical File revision.

The applicant declares,

- That the products mentioned above is in conformity with the respective regulations of the Medical Device Directive 93/42/EEC and its transpositions in national laws which apply to it;
- To fulfill the obligation imposed by the quality system approved;
- That no application has been lodged with any other notified body the same product-related quality system;
- To submit to the Notified Body the complete documentation on the Quality Management System and the necessary documentation on the product information which have to be evaluated (technical documentation);
- To fulfill the obligation imposed by the quality system approved;
- To keep the approved quality system adequate and efficacious;
- To institute and keep up to date a systematic procedure to review experience gained from devices in the post-product phase and to implement appropriate means to apply any necessary corrective action;

This declaration of conformity is valid from March, 18th 2021.

Rafael Holzhacker
Timpel S.A. President
For the Manufacturer

DC.210.01D_EN - Declaration of Conformity MDD - ENLIGHT 2100

Relatório de auditoria final 2021-03-18

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