Declaration of Conformity

MEDICAL DEVICE DIRECTIVE 93/42/EEC amended by the 2007/47/EC

We, Fremon Scientific, manufacturers of ZipThaw™202 device intended for thawing of Frozen Plasma, as detailed hereunder, that are placed in the European market, declare that our products conforms and meets the essential requirements set out in Annex I, the standards that detailed in table 1 and according to design requirements set out in Annex II of the Medical Device Directive 93/42 EEC.

We have appointed BSI Group, ID 0086 Kitemark Court, Davy Avenue, Milton Keynes MK5 8PP, United Kingdom, to act as our notified body.

Table 1 - Standards and technical specifications applied to prove the conformity with essential requirements

No.	Description	Standard	Latest Harmonized revision (Y/N)
1.	MDD Council Directive concerning medical devices	93/42/EEC including 2007/47/EC amendment	Y
2.	Medical devices -- Quality management systems -- Requirements for regulatory purposes	EN ISO 13485:2016	Y
3.	Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems	IEC 60601-1:2006 / EN 60601-1:2013	Y
4.	Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests	IEC EN 60601-1-2: 2015	Y
5.	Risk management for medical devices	EN ISO 14971: 2012	Y
6.	Medical Electrical Equipment - Part 1-6: General requirements for basic safety and essential performance	IEC 60601-1-6:2010	Y
7.	Medical devices -- Symbols to be used with medical device labels, labelling and information to be	ISO 15223-1: 2016	Y

No.	Description	Standard	Latest Harmonized revision (Y/N)
	supplied -- Part 1: General requirements		
8.	Information supplied by the manufacturer with medical device	EN 1041:2008	Y
9.	Clinical Investigation of Medical Devices for Human Subjects	EN ISO 14155:2011	Y

Product	**Classification**	**Followed**
ZipThaw™ 202	I	Annex IX Rule1

Within those requirements we prepared the required technical documentation, put into place corrective action and vigilance procedures and have appointed:
QsiteEU, Gerrit van der Veenstraat 84HS, 1077 EL Amsterdam, The Netherlands
to act as our Authorized Representative in the European Community.

We state that this declaration of conformity is valid for ZipThaw™ 202 as long as no changes in the products are done.
In case of any changes in the product, new revised declaration will be issued.

Position: Quality manager

Name: Galit Krepisman Date: 27/05/2019

Signature: _____ Valid Until: 27/05/2021