Declaration of Conformity

MEDICAL DEVICE REGULATION (EU) 2017/745

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 conform and meets the general safety and performance requirements set out in Annex I of Medical Device Regulation 2017/745.

Product	Classification	Followed	UDI-DI
ZipThaw™ 202 (P/N 44700)	I	Annex VII, chapter III, rule 1	72901152744700NS

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 ZipThawTM 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.

Farideh Bischoff

CEO, Dr. Farideh Bischoff

January 16, 2022

Date

Valid Until: 25/05/2024