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Manufacturing Solutions

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CONFORMITY CERTIFICATION FOR THE BioSint PRODUCT THAT IT COVERS THE TRANSITIONAL PROVISIONS ACCORDING TO REGULATION (EU) 2023/607

I hereby declare that the medical technology product BioSint, category IIa, has a Certificate

EC/CE CERTIFICATE issued in accordance with Directive 93/42/EEC from May 25 2017, with issue date: 04/04/2018 and expiration date: 04/03/2023, and was still in effect on May 26, 2021.

Therefore, in accordance with the provisions of Regulation (EU) 2023/607 on the amendment of

of regulations (EU) 2017/745 and (EU) 2017/746 regarding the transitional provisions for certain

medical devices and in vitro diagnostic medical devices, it is allowed to placed on the market or in use by 31 December 2028.

At the same time, we confirm that the following conditions are also met:

a) The BioSint medical device still complies with Directive 93/42/EEC

b) there are no significant changes in its design and intended use

c) does not present an unacceptable risk to the health or safety of patients, users or

of other persons or for other aspects of public health protection

d) an ISO 13485 management system will has been implemented

e) a formal application has been submitted to a notified body for assessment of compliance with regard to

BioSint technology product

Sincerely,

Stroumbos K. Charalambos

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