

Transamerican Technologies International dba TTI Medical
220 Porter Drive, Suite 120
San Ramon, CA 94583-9206
United States of America

Haaren, 30 July 2021.

This declaration is to clarify that QNET B.V. has formally accepted the renewed appointment as the EU Authorized Representative (EAR) for legal manufacturer Transamerican Technologies International dba TTI Medical, officed based at 220 Porter Drive, Suite 120, San Ramon, CA 94583-9206 (USA), as required by the EU Directive MDR 2017/745. The legal manufacturer may use QNET's name and address as the EAR for the CE-marked medical devices represented by QNET B.V.

This representation, including the information on the medical devices represented, is subject to the terms and conditions stated in the EU Authorized Representative Agreement signed between our two companies.

When you start to place the above-mentioned medical devices on the EU market, please make sure to properly affix the CE-marking on the medical devices, the labeling, packaging, inserts, and or other accompanying materials according to the related EU Directives and guidelines which have already been provided to you.

Please be advised that QNET B.V. is not involved in the design, manufacture, marketing, distribution, sales, supply, and or installation of your medical devices, it is, therefore, your responsibility to provide the instructions for use (IFU), if appropriate and required by the legislation of the EU Member States, in the official language(s) of the EU Member State(s) in which the medical devices are placed in the market. You need to provide us with the correct, accurate and most updated technical documentation per medical device family group, including IFU, per EU Decision No 768/2008/EC, prior to any shipment of your medical devices, which carry the name of QNET B.V. as the EU Authorized Representative, to the EU market.

Please inform us immediately whenever there is a change in either the above-mentioned medical device(s) or your company details so that we can update your CE-marking documentation promptly and adequately.

Sincerely,

Drs. A.H.G.M. Denissen, PRRC/QP

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