PIE MEDICAL IMAGING

solutions in cardiovascular analysis

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DECLARATION OF CONFORMITY
CAAS IntraVascular

We hereby declare that the distributed CE marked products, specified in the annexed product list, conform to the product(s) covered by the *CE Marking of Conformity Certificate* reference number G1 17 09 98021 005, initially issued on 2 December 2017, expiration date 1 December 2022 and delivered by TÜV SÜD Product Service Gmbh, Ridlerstrasse 65, 80339 Munich - Germany, Notified Body Identification Number 0123, in accordance with annex II of the law "*Besluit Medische Hulpmiddelen*" of The Netherlands, transposing the *EC Directive*, the council Directive 93/42/EEC of 14 June 1993, as amended by Directive 2007/47/EC, concerning medical devices.

In addition, we ensure and declare that the distributed CE marked products, as mentioned and falling within Class IIa, meet the provisions of the EC Directive that apply to them.

This declaration is based on the application of the Quality System approved for the design, manufacture and final inspection of the products concerned, in accordance with annex II of the EC Directive. The conformity of the full quality system set out in annex II, is described in the above-mentioned *CE Marking of Conformity Certificate*, issued and delivered by TÜV SÜD Product Service Gmbh.

This declaration is supported by the quality system certification based on the standard EN ISO 13485:2016, Quality System Certificate with reference number Q5 098021 0004, initially issued on 29 July 2020, expiration date 17 August 2023 and delivered by TÜV SÜD Product Service Gmbh.

Pie Medical Imaging B.V. is exclusively responsible for this Declaration of Conformity, which covers diagnostic imaging and processing software CAAS IntraVascular specified in the device configuration list belonging to this declaration, and is valid for all products concerned bearing the CE marking and manufactured at the in the header mentioned site.

Maastricht, 12 August 2020

P.M. Tulp
Quality Assurance Manager

Annex: 'Device Configuration List CAAS IntraVascular' [QA883]

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