Declaration of Conformity

Application of Council Directive(s): 93/42/EEC for Medical Devices

Device Classification: Class I, Rule 12

Standard(s) to which Conformity is Declared: Annex VII of MDD 93/42/EEC Council Directive

Manufacturer's Name: Foresight Imaging, LLC.

Manufacturer's Address: 1 Executive Drive, Suite 202
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Authorized Representative: QualRep Services B.V.
Utrechtseweg 310 Bldg 42
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Year of Manufacture: 2022

Model names:
TIMS 500 S, TIMS 2000 EN, TIMS 2000 SP, TIMS 2000 FEES, TIMS Review, TIMS Connect

We, the undersigned, hereby declare under our sole responsibility that the products above to which this declaration relates, are in conformity with the above Directives, Standards, and other normative documents. The products defined herein were manufactured under the conditions of the European Standards.

Place: Foresight Imaging, LLC

Date: June 17, 2022

Steven Tufo
(Signature)

Steven Tufo
(Full Name)

Manager of Compliance
(Position)

QualRep Service B.V.
(Authorized Rep)

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