

Declaration of Conformity

Manufacturer	Acutus Medical, Inc. 2210 Faraday Ave, Suite 100 Carlsbad, CA USA 92008
European Representative	HealthLink Europe BV De Tweeling 20-22 5215 MC 's Hertogenbosch The NETHERLANDS
Product Name	Qubic Force Sensing Module
Model Number	900012-002, 457793
Classification	Class IIb, per Rule 9 according to Annex IX of the Medical Devices Directive 93/42/EEC

We herewith declare in sole responsibility that as of the date of this declaration, the above-mentioned product meets the provisions of the following EC Council Directives and Standards. All supporting documentation is retained under the premises of the manufacturer and the notified body.

Directives:

Medical Device Directive: Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (MDD) as amended by 2007/47/EC, including Annex II

Directive 2011/65/EU of the European Parliament and of the Council of 08 June 2011 on the restriction of the use of hazardous substances in electrical and electronic equipment

Standards:

Harmonized Standards (published in the Official Journal of the European Communities) applicable to this product are: EN ISO 13485: 2016, IEC 60601-1:2005 + A1:2012 (EN 60601-1:2006 + AC/2010 + A1:2013); IEC 60601-1-2: 2014 (EN 60601-1-2:2015); IEC 62366:2007 (EN 62366:2008); IEC 60601-2-2:2009 (EN 60601-2-2:2009); IEC 62304:2006 + AC :2008 (EN 62304:2006 + AC :2008); EN ISO 14971:2012; ISO 15223-1:2012; DIN EN 980:2008; DIN EN 1 041:2008; IEC 60529:2009 + Corr. 3:2009

Notified Body:	DQS Medizinprodukte GmbH August-Schanz-Straße 21 DE-60433 Frankfurt am Main GERMANY Notified Body number: 0297
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Certificate:	506478, unique ID 170768547
Conformity Assessment Route:	Annex II
Valid Until:	2024-04-10
Place of Issue:	Carlsbad, CA, USA

These products are also in conformance with the technical documentation according to Annex III, Module B of the Directive 2014/53/EC (RED, OJ L 153/62) for the following EU type examination certificate:

Registration No.: G0M-1611-6027-V01
Certification Body: Eurofins Product Service GmbH, Storkower Strasse 38c,
15526 Reichenwalde b. Berlin, Germany
EEC No.: 0681
Date of Issue: February 13, 2017

Applied Standards according to Directive 2014/53/EU (RED):

3.1a EN 62311:2008
3.1b EN 301 489-1 V2.1.1:2016-11
EN 301 489-3 V2.1.1:2016-09
3.2 EN 300 330 V2.1.1:2016-11

Signed



Date

2 Nov 2020

Chris Reiser PhD, Vice President, Quality Assurance