



EUROPEAN DECLARATION OF CONFORMITY

InTouch Technologies, Inc., dba InTouch Health®
7402 Hollister Ave.
Goleta, CA 93117
U.S.A.

declares under our sole responsibility that the product

InTouch Lite 4 Telemedicine System

to which this declaration relates is in conformity with the following standard(s) or other normative document(s):

Directive 93/42/EEC Annex I

Conformity Assessment:

Council Directive 93/42/EEC of 14 June 1993 concerning medical devices and Annex II

Device Classification: N/A, does not meet the definition of a medical device

Directive 2011/65/EU

RoHS2

Council Directive 2011/65/EU of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment

IEC 60601-1-2:2014 Ed. 4 Medical Electrical Equipment – Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests

IEC 62366:2007 Ed. 1+A1 Medical Electrical Equipment – Part 1: General Requirements for Basic Safety & Essential Performance

IEC 60601-1-6: 2010 Ed. 3+A1 Medical Electrical Equipment – Part 1-6: General Requirements for Basic Safety and Essential Performance Collateral Standard: Usability

IEC 62304:2006 Ed. 1+A1 Medical Device Software – Software Life Cycle Processes

IEC 60601-1:2005 Ed. 3+A1 Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance

BS EN ISO 14971:2012 Medical Devices – Application of Risk Management to Medical Devices

EN 60601-1-2:2007 Medical electrical equipment – General Requirements for Basic Safety and Essential Performance – Collateral standard: Electromagnetic compatibility – Requirements and tests

EN 62353:2008 Medical electrical equipment: Recurrent test and test after repair of medical electrical equipment

EN ISO 13485:2016 Medical Devices. Quality Management Systems. Requirements for Regulatory Purposes

ETSI EN 301 489-1 V2.2.0 (2017-03)
ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU and the essential requirements of article 6 of Directive 2014/30/EU

ETSI EN 301 489-9 V2.1.1 (2017-03)
ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 9: Specific conditions for wireless microphones, similar Radio Frequency (RF) audio link equipment, cordless audio and in-ear monitoring devices; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU

ETSI EN 301 489-17 V3.1.1 (2017-02)
ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific Conditions for Broadband Data Transmission Systems; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU

CSA C22.2#60601-1:2014Ed.3 Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance

-AAMI ES60601-1:2005+A1 Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance

-IEC 62368-1:2014Ed.2+C1 Audio/Video, Information and Communication Technology Equipment - Part 1: Safety Requirements

-UL 62368-1:2014Ed.2 Audio/Video, Information and Communication Technology Equipment - Part 1: Safety Requirements

-CSA C22.2#62368-1:2014Ed.2 Audio/Video, Information and Communication Technology Equipment - Part 1: Safety Requirements

-IEC 62366:2007Ed.1+A1 Medical Devices - Application of Usability Engineering To Medical Devices

-IC ICES-003:2016Ed.6 Information Technology Equipment (Including Digital Apparatus) – Limits and Methods of Measurement

-EN 55035:2017 Electromagnetic Compatibility of Multimedia Equipment - Immunity Requirements

-IEC 60950-1:2005Ed.2+A2012;C2012 Information Technology Equipment Safety Part 1: General Requirements

-EN 61000-3-3:2013 Electromagnetic Compatibility (EMC) -Part 3-3: Limits -Limitation of Voltage Changes, Fluctuations & Flicker In Public Low-Voltage Supply Systems For Equipment With Rated Current ≤ 16 A Per Phase & Not Subject To Conditional Connection

-EN 61000-3-2:2014 Electromagnetic Compatibility (EMC) -- Part 3-2: Limits - Limits for Harmonic Current Emissions (Equipment Input Current ≤ 16 A Per Phase)

-CENELEC EN 55032:2012 Electromagnetic Compatibility of Multimedia Equipment – Emission Requirements

-AS/NZS CISPR 32:2015 Electromagnetic Compatibility of Multimedia Equipment - Emission Requirements

-CISPR 32:2015 Ed.2.0 Electromagnetic Compatibility of Multimedia Equipment - Emission Requirements

Date of issue: 13 May 2020

Date of Expiration: 12 May 2023

Place of issue: Santa Barbara, California, USA

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