

To whom it may concern

## General Statement of Compliance

We hereby confirm that Ascom Wireless Solutions' design and development process for Medical Devices is in compliance with at least the following standards:

- ISO 13485 Medical devices - Quality management systems - Requirements for regulatory purposes
- ISO 14971 Medical devices - Application of risk management to medical devices
- IEC 80001-1 Application of risk management for IT-networks incorporating medical devices – Part 1: Roles, responsibilities and activities
- IEC 62366 Medical devices - Application of usability engineering to medical devices
- IEC 62304 Medical device software - Software life-cycle processes

Ascom Wireless Solutions products are designed to conform to a large number of standards, including but not limited to harmonized standards under applicable EU directives. Testing is performed internally at Ascom and/or by third party test houses.

Declarations of Conformity for each product are available on the Internet at [www.ascom.com/ws](http://www.ascom.com/ws).

Göteborg, 10 January 2013



Anders Melin

Vice President  
Supply Chain, IT and Quality

Ascom (Sweden) AB



Stefan Brämberg

Chief Technology Officer (CTO)

Ascom (Sweden) AB