

STATEMENT

of Calibration and QA



This is to certify that Bolls ApS/Bolls Rådgivning is a qualified 3. party testing laboratory under the following EC directives:

2014/30/EU Electromagnetic Compatibility Directive
2014/35/EU Low Voltage Directive
2006/42/EU Machinery Directive
93/42/EC Medical Device Directive (+ modifications)
2014/53 Radio Equipment Directive

Company:

Bolls ApS (Bolls) is a registered Corporation in Denmark and holds legal responsibility for its operation. (VAT No.: DK-33766696)

Bolls is a privately held company, not part of any other company or organization.

Bolls is organized to operate in accordance with the requirements of ISO/IEC 17025, whether carrying out work in its permanent facilities or at off-site locations. It is the responsibility of all employees to work in accordance with the quality policies while satisfying the needs of our clients.

Bolls is not part of an organization performing activities other than testing/consulting; therefore, there is no potential conflict of interest amongst its personnel and/or customers.

Human resources:

Personnel working at Bolls are appropriate educated, trained and have appropriate skills and experience.

Personnel have been trained at:

UL
CSA
ETL

These skills are maintained by participating in the following standardization work and ERFA groups;

DS S-562 / IEC TC62 concerning electro medical device
TC62/SC 62A/WG14 Testing to General Safety Standard
TC62/SC 62A/MT23 EMC electro medical device
DS S-534 / IEC TC 34 Luminaires
DS S-710 / IEC TC 77 EMC
SPM ERFA group 5 Product safety
SPM ERFA group 9 EMC

Test equipment:

Test equipment calibration are subcontracted to an ISO 17025 accredited calibration laboratory traceable to national (DANAK) and international calibrations norms.

DANAK has linkages with international bodies like International Laboratory Accreditation Co-operation (ILAC), European co-operation for Accreditation (EA) and International Accreditation Forum Inc. (IAF). Tests are performed according to ISO 17025 requirements.

A few instruments are calibrated at Bolls by using external calibrated instruments.

Date:

Slagslunde: 03-09-2019

Certified by:



Manager; Kim Boll Jensen

Bolls ApS Ved Gadekæret 11F DK-3660 Stenløse Denmark