

Regulatory Compliance across the World

- Regulatory Affairs
- Quality Management
- Regulatory Intelligence
- Design Controls



Declaration of Conformity

Medicologic A/S declares that our Quality Assurance, Regulatory Affairs and Design & Development consultancy services are in compliance with current applicable Legislation Requirements and Standards.

Comply with:

The European Council Directive 93/42/CE modified 2007/47/CE.

Transition to:

MDR regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017
IVDR regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017

(Applicable) harmonized standards:

ISO 9001
ISO 13485
ISO 14971
ISO 15986
ISO 15223
ISO 15378
ISO 11737
ISO 11135
ISO 11607

May, 2019 - Michael Funder, CEO, Medicologic A/S