Declaration of Conformity

We, RTI Group AB, Flöjelbergsgatan 8C, SE-431 37 MÖLNDAL, Sweden, declare under our sole responsibility that the product:

Product name:	Mako
Models and accessories:	According to Appendix 1
Type of equipment:	X-ray multi-meter
Intended use of this product:	According to Appendix 2

Conforms with the provisions of the following EC Directive(s):

- **2014/30/EU Electromagnetic Compatibility (EMC) Directive**
- **2014/35/EU Low Voltage Directive (LVD)**
- **2014/53/EU Radio Equipment Directive (RED)**
- **2015/863/EU Restriction of Hazardous Substances in EEE Directive (RoHS 3)**

and that the following standards and/or technical specifications referenced below have been applied:

EN 55032/B, EN 55016, EN55035, EN 61000-3-2,
EN 61000-3-3, EN 61000-4-2, EN 61000-4-3, EN 61000-4-4,
EN 61000-4-5, EN 61000-4-6, EN 61000-4-11,
EN 62368-1 + A11:2024, EN 300 328, EN 301 489-1-3

CE

Mölndal, 2025-06-05

Elin Sahlberg, CEO

RTI Group Headquarters
Flöjelbergsgatan 8C
SE-431 37 Mölndal, SWEDEN

Phone: +46 (0) 31 746 36 00
info@rtigroup.com
www.rtigroup.com

Company registration number: 556230-2462
VAT number: SE556230246201

Declaration of Conformity - Appendix 1

Mako system modules

Base Unit,	BU-2309001 and beyond
R/F Probe,	MDR-2309001 and beyond
Mammo Probe,	MDM-2309001 and beyond
Dental Probe,	MDD-2309001 and beyond
mAs Module,	IMM-2309001 and beyond
Ion Chamber Module,	ICM-2309001 and beyond
Legacy Module,	LDM-2309001 and beyond

Accessories

Probe's name	*Notice*
RTI Dose Probe	s/n: 1403099 and above
RTI T20, Dose Probe	
RTI Light Probe	
RTI MAS-1	product version 3.0
RTI MAS-2	
RTI CT Dose Profiler	product version 2.0
RTI CT Ion Chamber 10 cm	
RTI CT Ion Chamber 30 cm	
Ion Chamber Magna 1cc	
DAP Chamber 147x147 mm	
DAP Chamber 86x86 mm	
Mako mAs Cable	

Declaration of Conformity - Appendix 2

Intended use

Together with external probes, the Mako System is intended to be used for independent service and quality control, including measurements of kerma, kerma rate, kVp, tube current, half value layer (HVL), exposure time, luminance, illuminance, dose length product and dose area product, within limitations stated below.

When set up according to accompanying documents, the product is intended to be used together with any diagnostic X-ray equipment except for:

- therapeutical X-ray sources.
- X-ray equipment with tube potential below 18 kV or above 160 kV.
- X-ray equipment on which the instrument cannot be mounted properly.
- specific types of X-ray equipment listed in the instructions for use or in additional information from the manufacturer.

With the X-ray installation without the patient present, the product is intended to be used:

- for assessing the performance of the X-ray equipment.
- for evaluation of examination techniques and procedures.
- for service and maintenance of the X-ray equipment.
- for quality control of the X-ray equipment.
- for educational purposes, authority supervision etc.

The product is intended to be used by hospital physicists, X-ray engineers, manufacturer's service teams, and other professionals with similar tasks and competencies. The operator needs training to be able to use the product as intended. This training can be achieved either by study of the manual, study of the built-in help functions in measurement software or, on request, by a course ordered from the manufacturer.

The product is intended to be used inside X-ray rooms ready for clinical use and can safely be left switched on and in any measuring mode in the vicinity of patients.

The product is **NOT** intended to be used:

- for direct control of diagnostic X-ray equipment performance during irradiation of a patient.
- so that patients or other unqualified persons can change settings of operating parameters during, immediately before, or after measurements.
- for any guidance to diagnosis of patients.