Declaration of Conformity

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

Product name:	RTI Scatter Probe
Model part number:	9631001-00
Type of equipment:	Scatter radiation detector
Intended use of this product:	According to appendix 1

is in conformity with the provisions of the following EC Directive(s):

- **2014/30/EU Electromagnetic Compatibility** (EMC) **Directive**
- **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 61000-4-2
EN 61000-4-3
EN 62368-1 + A11

CE

Mölndal, 2025-07-09

Elin Sahlberg, CEO

INDEPENDENT X-RAY QUALITY ASSURANCE

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Declaration of Conformity - Appendix 1

Intended Use of the RTI Scatter Probe

The RTI Scatter Probe is intended to be used for independent service and quality control, including measurements of air kerma, air kerma rate, Ambient dose equivalent, mean energy, half value layer, and time, within limitations stated below.

When installed according to accompanying documents, the product is intended to be used in the area surrounding medical X-ray equipment except for:

- X-ray equipment with tube potential below 18 kV or above 160 kV.
- 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 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 or, on request, by a course ordered from the manufacturer.

The product is intended to be used in the area in and around 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.