

Confirmation of Conformity

PRIMAX Berlin GmbH, Meeraner Straße 17e, 12681 Berlin, Germany herewith confirms that the product:

Category: X-ray film, medical, screen (class IIa product)
Trade name: PRIMAX RDX-58 E
Application: Intra Oral Dental Radiology

- comply with the requirements of the 93/42/EEC Directive (Medical Device) via the Swedish Law Legislation LVFS 2003:11.
- that for the a.m. class IIa products the procedures of Annex VII in combination with the procedures of Annex V have been applied in order to mark the products with the CE label.

The notified body involved in the above specified procedures is Intertek Semko AB holding the registration number 0413.

This declaration is valid for maximum 3 years from signature date.

Date of issue:

Berlin, 16th June 2021

Solveig Wolthusen
Managing Director

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