



EC DECLARATION OF CONFORMITY

Here we,

J. MORITA MFG. CORP.

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declare under own responsibility, that the product;

Kind of Product:

Apex Locator

Product Name:

Root ZX mini / S-Apex / Endostar Navigator

Model:

RCM-7

Type:

Medical Product Class:

Class IIa as Rule 9

UMDNS Code:

16-355 (Apex locators, Endodontics)

is in compliance with the European Directive,

93/42/EEC

Counsil Directive of 14 June 1993 on the approximation of the laws of the Member States concerning medical devices.

The compliance with requirements of EC Directive 93/42/EEC Annex II has been approved by the following notified body:

Notified Body:

TÜV Rheinland LGA Products GmbH

Tillystrasse 2, 90431, Nuremberg, Germany

Identification No. 0197

Registration No.: HD 60147054 0001

EU Authorized Representative:

Medical Technology Promedt Consulting

Altenhofstrasse 80, 66386 St. Ingbert, Germany

This declaration of conformity is related to each product release document.

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Kyoto, Japan

Place

Date .

2020.12.2

Yoshihiko Yakashima

Yoshihila Talashiwa

Managing Director