EU Declaration of Conformity



Document No.: GI 137 / 18

Manufacturer and Address:

SIRONA Dental Systems GmbH

Fabrikstrasse 31 64625 Bensheim

Germany

SRN:

DE-MF-000000029

Medical Device Name:

Lubricants and care products

Basic UDI-DI:

++E276OilV01J4

Classification according to Annex VIII (2017/745/EU):

Class I, Rule 5

(2011/140/20).

None

Common Specifications:

Intended Use: Maintenance of dental instruments

We declare under our sole responsibility the compliance of the medical device concerned with the requirements of the Council Regulation 2017/745/EU.

Any modification to the product, not authorized by us, will invalidate this declaration.

Valid from manufacturing date: 2021-05-10

Bensheim: 10.05.2021

Place and date

Niels Plate

Group Vice President

Wolfram Müller

Regulatory Compliance Manager

4) Milles

The declaration certifies the compliance according to Annex I of Regulation 2017/745/EU. Conditions of guarantee and liability are dealt within our General Conditions of Sale.

EU Declaration of Conformity



Product Models / Types and Identification (Ref.-

T1 Spray 250ml 6 pieces, REF 5901665

Number):

T1 Spray 50 ml, REF 1894299

SiroBreeze, REF 6090786

Product variants / configurations: