

DECLARATION OF CONFORMITY

Rev. 2 Jan 2020

The manufacturer,

Company name:

Simple&Smart S.r.l.

Head Office:

Via Perola 16, 24021 Albino (BG)

VAT number:

04077160168

Product:

Dental Unit

Classification:

CLASS IIA REGULATION 9

In accordance with Annex

IX DIRECTIVE 93/42 CEE

Valutazione di conformità:

ANNEX V DIRECTIVE 93/42 EEC AMENDED BY DIRECTIVE 07/47 CE

Declares under its own responsibility

that the product named **SS_ITALO**

Serial Number:

Manufacturing date:

mentioned above and described in the technical file "dental unit" intended to be used for dental treatments:

- It is not a device with a measuring function,
- It is not sterile,
- Does not incorporate substances or medicines,
- It is not intended to administer and/or subtract medicines, body fluids or other substances from the body,
- Does not contain animal tissues,

complies with the essential requirements according to Annex I of the European Directive 93/42 amended by Directive 07/47 of medical devices.

Applicable standards: See point 14 of the technical file

Notified Body: BVQI Bureau Veritas S.p.A. - Viale Monza, 347 - 20126 MILANO

Identification number: CE 1370

EC Certificate nr.: IT261641-3

Original Certification Date: 03/07/2015

Current Certification issuing: 11/05/2021

Place: ALBINO

Date of issue: 17/10/2024

The legal representative
(responsabile rilascio del prodotto)
Dr. Cris Noris

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