



BUREAU
VERITAS

Bureau Veritas Certification

EU quality assurance certificate

Issued to

SIMPLE & SMART SRL

VIA PEROLA, 16 – 24021 ALBINO (BG) - ITALY

Single Registration number: **IT-MF-000029732**

Certified site(s)

VIA SAN CARLO 33/35 – 24029 VERTOVA (BG) - ITALY

Bureau Veritas Italia S.p.A. certifies that the production quality assurance system of the above mentioned manufacturer has been audited and it complies with the requirements of

Regulation (EU) 2017/745

(in accordance with annex XI part A)

In relation to the following Medical Device(s):

Model name (s):	SS_ONE, SS_KISS, SS_ITALO
Generic group	Dental unit
Category	MDA0311 - Active non-implantable dental devices
Risk class	Ila
Basic UDI-DI	805776025FT01SSC7
Specific conditions or limitations of validity of the certificate	None

Certificate issue date: **14/11/2024**

Subject to the continued satisfactory operation of the production quality assurance system, this certificate expires on: **13/11/2029**

Certificate N°: IT337342 Version: 1

Issue date: **14/11/2024**

Revision History	
Revision	Description
Revision n. IT337342-1 Revision date: 14/11/2024	CER-F-093 17773484_1-19277533868 rev.01 dated 14/11/2024: First issue approval


GLORIA FOCETOLA - Local Technical Manager

This certificate is issued by Bureau Veritas Italia S.p.A. Viale Monza 375- 20126 Milano ITALY, notified body according to the Regulation (EU) 2017/745 with identification number 1370.

Information on examinations and tests performed regarding relevant CS and harmonized standards, relevant test reports and audit report(s) are in the dossier (FLEX n. 17773484) available on request from medical.device@bureauveritas.com