bioloren
metal free dental system

bioloren srl
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bsi. ISO 13485 Medical Devices Quality Management
MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM

DECLARATION OF CONFORMITY

Nastimed
Str. M. Emmescu 1
400033 Cluj Napoca- Romania

Bioloren company, registered office in Saronno (VA), street Alessandro Volta 59, manufacturer of the medical devices family **"Endodontic posts" (Certificate n° 29691, Expiry date: 26/05/2024),** declares under its own responsibility that the devices, defined in the specific technical files and called:

DESCRIPTION	LOT NUMBER
Fiber post translucent conical 2% with colour code Ø 1,2-1,65 mm.	23/07
Fiber post translucent conical 2% with colour code Ø 1,4-1,85 mm.	23/02
Kit fiber post translucent conical gripper	22/03
Kit fiber post translucent conical 2% with colour code	22/03

meets all essential requisites required by paragraph I of Directive 93/42/EEC on Medical Devices and following modifications, as outlined in paragraphs VII and V of the above mentioned Directive.

CE marking according to Directive 93/42/EEC transposed by Legislative Decree No. 46/97 and following modifications.

To this purpose it guarantees and declares, under its own responsibility what follows:

(1) that the device in hand stands by the directions in force of Directive 93/42/CEE and following modifications, Directive 2007/47 and following modifications, EN ISO 13485:2016, UNI CEI EN ISO 14971:2020, UNI CEI EN ISO 15223-1:2017;
(2) that the device in hand is to be considered as belonging to class IIa (according to annex IX to Directive 93/42/EEC and following modifications);
(3) that the device in hand is marketed in no sterile pack;
(4) that no request for certification of the same products has been made to any other Notified Body;
(5) that the manufacturer commits itself to keeping the technical documentation as to point 3 of paragraph VII and to point 5 of paragraph V of Directive 93/42/CEE available to the Notified Body Certiquality (CE 0546) street Gaetano Giardino 4, 20123 Milano (MI) Italy, for a period of 10 years for the date of product manufacturing. The above mentioned documentation supports the present conformity declaration. The documentation is kept by the Quality Manager at the Company's registered office;
(6) that the manufacturer undertakes to maintain a post-market surveillance procedure;
(7) that the device in hand is manufactured in accordance with the above mentioned technical documentation.

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Signature: .....
Name: Silvia Ratti
Position: Quality Manager
Date: Saronno, 07.06.2023

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