

	<p>Red Pill S.r.l.</p> <p>Headquarters: Via Milano, 50 – 25064 – Gussago (BS)</p>
<p>Document: Declaration of conformity</p>	

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Drawn up
Alessandro Fogazzi
Date: 27/11/2018

REVIEW		
Review	Review reason	Date
1	First issue	29/11/2018

This document “Declaration of conformity” has been issued under the full manufacturer responsibility.



Declaration of conformity

The undersigned Alessandro Fogazzi

As legal representative of the company Red Pill S.r.l.

headquarters: Via Milano, 50 – 25064 – Gussago (BS)

VAT: 03772180984

Declares

That the product: endodontic organizer

Model and code: Plano - 8058093832536

Medical device class: I

Vector UDI-DI: 8058093832536

Date/ manufacture year: 2018

Lot number: XXXXXX

It was built in compliance with the following directives and standards:

- Regulation (UE) 2017/745 relating to Medical Devices
- Directive 2001/95/EC known as "General Product Safety Directive"
- UNI CEI EN ISO 14971:2012 – Medical devices – Application of risk management to medical devices.
- Standard IEC 61882:2016 risk analysis method following HAZOP study procedure
- Dir. 93/42 / CEE D.L. 24/02/97 nr. 46 D.L. 25/02/98 nr. 95 Council Directive concerning medical devices, implementation of Directive 93/42 / EEC concerning medical devices. Changes to the Legislative Decree 24 February 1997 nr. 46 (which will coexist with the new Regulation until 2020)
- Dir. 2007/47 / CEE D.L. 25/01/10 nr. 37 Council Directive concerning medical devices Implementation of Directive 93/42 / EEC concerning medical devices. (which will coexist with the new Regulation until 2020)
- UNI CEI EN 980:2009 Graphic symbols used for the labeling of medical devices
- UNI CEI EN ISO 15223-1:2012 Symbols to be used in the medical device labels, labeling and information to be provided - Part 1: General requirements
- UNI CEI EN 1041:2009 Information provided by the Manufacturer with medical devices

It complies with directives and regulations in force.

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

Signature:



Via Lauro, 95 Cadoneghe Padova Italy
Advisors and Experts for: Guardia di Finanza, Tributaria, Autorità Doganali, Carabinieri,
Polizia di Stato, Unioncamere, Tribunali.

The correct constitution of the technical dossier, as well as the documents prepared by C&C s.a.s., have been verified by Eng. Renato Carraro.

Notes

- The declaration of conformity on page 2 of this document must ALWAYS accompany the product when it is made available to a third party in any form (sale, loan for use, loan, etc.)
- Only page 2 must accompany the product. Never deliver the first page and notes of this page.
- **The rules governing the product must be respected and indicated if the presumption of compliance with the directives is to be confirmed. The lack of reference to the standards can lead the authorities to request the test.**
- The risk analysis of which we provide a complete model to the examined product, has been carried out based on standards we indicated in the document and written in black (ex. Standard IEC 61882:2016 risk analysis method following HAZOP study procedure).