Procedure Pack Declaration of Conformity as per MDR 2017/745 Article 22

Procedure pack producer:	PRODUITS DENTAIRES SA Rue des Bosquets 18 1800 Vevey Switzerland
SRN:	CH-PR-000045775

European Authorized Representative	PD Dental EU Rue des Arcouasses 4 Thonon-les-Bains, 74200 France
European Authorized Representative SRN	FR-AR-000017144

We declare under our sole responsibility that, for the following procedure pack:

Irriflex PP

(a) We have included only devices which are CE marked.

(b) We have verified the mutual compatibility of the devices in accordance with the manufacturers' instructions

(c) We have packaged the procedure pack in a way that maintains conformity and integrity of all included devices.

(d) We have incorporated the necessary and applicable information to be supplied by manufacturers for each contained device.

(e) The activity of combining devices as procedure pack was subject to appropriate methods of internal verification and validation.

(f) No repackaging or modification of the individual devices has been made.

(g) No additional risk is introduced by combining the devices.

Description of the devices included for each procedure pack:

Irriflex ***Ref: 21401_PP*** ***UDI-DI: 07640159163626***				
Item No.	**Device Name**	**Manufacturer**	**UDI-DI**	**Class**
21401	Irriflex (40)	Produits Dentaires SA	07640159160120	IIa
21407	Endostops (50)	Polydentia	+E29921407	I

Quality & Regulatory Manager Silvia Contini

Vevey, 2025-07-25