INJECTION SYSTEMS

JUVA+

EC DECLARATION OF CONFORMITY

Manufacturer's Name:	JUVAPLUS SA
Manufacturer's Address:	Rue du Pré, 10 2114 Fleurier (NE) Switzerland

I, undersigned, declare that the Medical Device DENTAPEN, its accessories and consumables bearing the CE marking, conforms with the essential requirements of the Directive 93/42/EEC annex I, as amended.

Product Name	Product Description	Classification
DENTAPEN	Automated injection system designed for local injections of dental anesthesia	Class IIa According to Annex IX Rule 11
DENTAPEN accessories & consumables	- Finger grip, Finger grip Spix, Cartridge holder - Protective sleeves, Batteries, O-rings	Class I According to Annex IX Rule 1

The EC marking has been affixed on DENTAPEN according to Annex II excluding section 4 of the EC Directive 93/42/EEC and certified by:

Notified Body	DNV GL PRESAFE AS - Veritasveien 3, N-1363 Høvik, Norway Identification number: 2460
EC Certificate	239155-2017-CE-ITA-NA-PS Rev. 4.0 – September 12th 2019

JUVAPLUS compliance with ISO13485:2016 standard was certified by:

Notified Body	DNV GL Business Assurance Italia S.r.l Via Energy Park 14, 20871 Vimercate, Italy
ISO Certificate	164715-2014-AQ-ITA-ACCREDIA – July 26th 2019

Applicable harmonized standards have been used to demonstrate safety and efficacy of the devices when used according to JUVAPLUS' Instructions for Use. Each batch of product is released for sale in accordance with records certifying compliance with specifications.

Date: *September 17th, 2019*

Philippe COTIER
Chief Administrative, Quality & Operations Officer