

DECLARATION OF CONFORMITY

Product family:	ASIL1903_Bite Registration
Intended Purpose:	Jet Blue Bite is intended for the registration of occlusion in cases where relationship between the relative positions of maxilla and mandible is required.
Medical Device Name:	Jet Blue Bite
Basic UDI-DI:	76303929ASIL190313A
UMDNS /GMDN:	16-680 / 18083
EMDN:	Q010201
Classification:	Class IIa; (EU) 2017/745 Annex VIII, Rule 19 (3)
Legal Manufacturer:	Dent4You AG Bahnhofstrasse 2 CH-9435 Heerbrugg CHRN: CHRN-MF-20001009 SRN: CH-MF-000028926
European Representative:	Dent4You GmbH Raiffeisenstrasse 30 DE-89129 Langenau SRN: DE-AR-000006093

We herewith declare that the above-mentioned products meet the provisions of the following EC legislations and that Dent4You has exclusive responsibility for the content of this Declaration of Conformity. All supporting documentation is retained at the manufacturer's premises.

General Applicable Legislation:

Medical Device Regulations: Regulation (EU) 2017/745 of 5 April 2017 on medical devices (MDR 2017/745/EU, Annex IX excluding chapter II)

Standards and Common Specifications:

EN ISO 13485:2016, EN ISO 14971:2021, ISO 10993-1:2018, EN ISO 7405:2019, ISO 4823:2021

Notified Body: TÜV SÜD Product Service GmbH
Ridlerstraße 65,
D-80339 München, Deutschland
Identification No. 0123

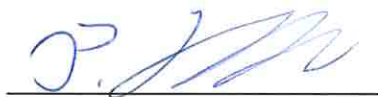
Certificate: G10 098596 0007

REF	UDI-DI	Description
6491	07630243635757	JET BLUE BITE FAST 50 ml
6495	07630243635764	JET BLUE BITE FAST 4 x 50ml
6493	07630243635771	JET BLUE BITE SUPERFAST 50ml
6497	07630243635788	JET BLUE BITE SUPERFAST 4 x 50ml

Place: Altstaetten, Switzerland

Valid to: 28/09/2026

Signature:



Date:

2024-03-26

Name & Title: Patrick Vortanz PRRC