

PENTRON

Annex V EC Declaration of Conformity

Manufacturer Name and Address: Pentron Clinical
1717 West Collins Ave.
Orange, CA, 92867 (USA)

Authorized Representative Name and Address: SpofaDental a.s.,
Markova 238
CZ-506 01 Jicin, Czech Republic

Technical File Name/Number: Project #116 and Technical File #R025

Product Tradename(s): Breeze

Device Identification: See Attachment 1

Classification and Rule(s): Class IIa – Rule 8

Notified Body: BSI Group The Netherlands B.V.
Notified Body Number: 2797
Conformity Assessment Procedure & Certificate Issued: Annex V – Production Quality Assurance
CE certificate: CE 00847

Declaration Statement:

We hereby declare that the above-mentioned device(s) comply with Council Directive 93/42/EEC.

Regulatory Affairs Signature:

23 September 2021

Issue date



Mark Dzendzel
Director, Quality Assurance Systems

PENTRON

Breeze Project #116 and Technical File #R025 Attachment 1 to Annex V EU Declaration of Conformity		
REF	Description	
N97	Breeze – Self-Adhesive Resin cement Intro Kit	Orange
N97A	Breeze – Self-Adhesive Resin cement Translucent syringe	Orange
N97B	Breeze – Self-Adhesive Resin cement A2 syringe	Orange
N97E	Breeze – Self-Adhesive Resin cement Opaque White syringe	Orange
N97F	Breeze – Self-Adhesive Resin cement A2 syringe, sample	Orange