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 # DUX001 and DUX002 and Technical File #R032
Product Tradename(s):	Zone ZoneFree Zone A1
Device Identification:	See Attachment 1
Classification and Rule(s):	Class IIa – Rule 7
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:

13 October 2021
Issue date

Mark Dzendzel
Director, Quality Assurance Systems

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Zone / ZoneFree / Zone A1 Project #DUX001 and DUX002 and Technical File #R032 Attachment 1 to Annex V EU Declaration of Conformity	
REF	**Description**
27029DX	ZONEfree Unit Dose Pouches
27039DX	Zone Unit Dose Pouches
27040DX	Zone Temporary Cement Tubes – Base & Catalyst
27041DX	ZONEfree Automix Syringe
27042DX	ZONEfree Dual Barrel Syringe
27043DX	Zone Dual Barrel Syringe
27045DX	Zone Dual Barrel Syringe, A1
27046DX	Zone Automix Syringe, A1
27047DX	Zone Automix Syringe