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 #119 and Technical File #R033
Product Tradename(s):	TempSpan C&B
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:

08 October 2021
Issue date

Mark Dzendzel
Director, Quality Assurance Systems

PENTRON

TempSpan C&B Project #119 and Technical File #R033 Attachment 1 to Annex V EU Declaration of Conformity		
REF	**Description**	
N69AA	TempSpan Temporary C&B Material, AO	Orange
N69AB	TempSpan Temporary C&B Material, A1	Orange
N69AC	TempSpan Temporary C&B Material, A2	Orange
N69AD	TempSpan Temporary C&B Material, A3	Orange
N69AE	TempSpan Temporary C&B Material, A3.5	Orange
N69AF	TempSpan Temporary C&B Material, B1	Orange
N69AG	TempSpan Temporary C&B Material, C2	Orange