

Annex V EC Declaration of Conformity

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

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

Technical File Name/Number: Build-It FR, R035

Product Tradename(s): Build-It FR

Device Identification: See Attachment 1

Classification and Rule(s): IIa per Annex IX, 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 Number 00847

Declaration Statement:

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

Regulatory Affairs Signature:

01 October 2021

Issue date



Name: Mark Dzendzel

Title: Director, Quality Assurance Systems

**Build-It FR – Attachment 1
to Annex V EC Declaration of Conformity**

REF	Description
N32	BUILD-IT FR KIT
N32AA	BUILD-IT FR CARTRIDGE REFILL, A2
N32AB	BUILD-IT FR CARTRIDGE REFILL, GOLD
N32AC	BUILD-IT FR CARTRIDGE REFILL BLUE
N32AD	BUILD-IT FR CARTRIDGE REFILL, OPAQUE WHITE
N32AE	BUILD-IT FR CARTRIDGE REFILL, A3
N32F	BUILD-IT FR MINI MIX KIT
N32FA	BUILD-IT FR MINI MIX REFILL, A2
N32FB	BUILD-IT FR MINI MIX REFILL, A3
N32FC	BUILD-IT FR MINI MIX REFILL, GOLD
N32FD	BUILD-IT FR MINI MIX REFILL, BLUE
N32FE	BUILD-IT FR MINI MIX REFILL, OPAQUE WHITE
N32FAA	BUILD-IT FR MINI KIT 2 PACK, A2
N32FS	BUILD-IT FR SYRINGE REFILL, A2
N32FSA	BUILD-IT FR SYRINGE REFILL, A3
N32FSB	BUILD-IT FR SYRINGE REFILL, GOLD
N32FSC	BUILD-IT FR SYRINGE REFILL, BLUE
N32FSD	BUILD-IT FR SYRINGE REFILL, OPAQUE WHITE