

PENTRON

EC-Declaration of Conformity

Issuer's Name: Pentron Clinical

Issuer's Address: 1717 West Collins Avenue, Orange, CA 92867, USA

EU Representative: SpofaDental a.s., Markova 238, CZ-506 01 Jičín, Czech Republic

Object(s) of the Declaration: Flow-It ALC
(Class IIa)

Finished Article

<u>Number</u>	<u>Description</u>
N11WA	Flow-It ALC Flowable Composite Intro Kit
N11XA	Flow-It ALC Flowable Composite Syringe Shade A0
N11A	Flow-It ALC Flowable Composite Syringe Shade A1
N11B	Flow-It ALC Flowable Composite Syringe Shade A2
N11C	Flow-It ALC Flowable Composite Syringe Shade A3
N11J	Flow-It ALC Flowable Composite Syringe Shade A3.5
N11K	Flow-It ALC Flowable Composite Syringe Shade A4
N11XB	Flow-It ALC Flowable Composite Syringe Shade B0
N11L	Flow-It ALC Flowable Composite Syringe Shade B1

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By virtue of this declaration of conformity,
Pentron Clinical
ensures and declares

that the object(s) described above are Class IIa products according to Annex IX of Directive 93/42/EEC and are manufactured in conformity with the provisions of the Council Directive 93/42/EEC and the technical documentation referred to in Annex VII, Section 3 and Annex V as amended by 2007/47/EC,

thus, meeting the requirements of the Medical Device Directive as demonstrated by certificate CE 00847, issued by BSI, Notified Body no. 0086.

Directive 93/42/EEC has been implemented in the Czech Republic through Government Decree 336/2004 Coll. which determines technical requirements for medical devices, as subsequently amended.

Name: Mark Dzendzel

Function: Senior Quality Assurance Manager

Signature: 

Date: 9 March 2015

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Object(s) of the Declaration: Flow-It ALC
(Class IIa)

Finished Article

<u>Number</u>	<u>Description</u>
N11D	Flow-It ALC Flowable Composite Syringe Shade B2
N11E	Flow-It ALC Flowable Composite Syringe Shade B3
N11M	Flow-It ALC Flowable Composite Syringe Shade B4
N11N	Flow-It ALC Flowable Composite Syringe Shade C1
N11F	Flow-It ALC Flowable Composite Syringe Shade C2
N11G	Flow-It ALC Flowable Composite Syringe Shade C3
N11O	Flow-It ALC Flowable Composite Syringe Shade C4
N11H	Flow-It ALC Flowable Composite Syringe Shade CLEAR
N11P	Flow-It ALC Flowable Composite Syringe Shade D2
N11Q	Flow-It ALC Flowable Composite Syringe Shade D3
N11R	Flow-It ALC Flowable Composite Syringe Shade D4
N11XC	Flow-It ALC Flowable Composite Syringe Shade Incisal
N11U	Flow-It ALC Flowable Composite Syringe Shade Pedo Light
N11V	Flow-It ALC Flowable Composite Syringe Shade Pedo Extra Light
N11I	Flow-It ALC Flowable Composite Syringe Shade Universal Opaque
N11XD	Flow-It ALC Flowable Composite Syringe Shade White Opaque
N11VXA	Flow-It ALC Flowable Composite Syringe Value Pack Shade A0
N11VA	Flow-It ALC Flowable Composite Syringe Value Pack Shade A1
N11VB	Flow-It ALC Flowable Composite Syringe Value Pack Shade A2
N11VC	Flow-It ALC Flowable Composite Syringe Value Pack Shade A3
N11VJ	Flow-It ALC Flowable Composite Syringe Value Pack Shade A3.5
N11VK	Flow-It ALC Flowable Composite Syringe Value Pack Shade A4
N11VXB	Flow-It ALC Flowable Composite Syringe Value Pack Shade B0
N11VL	Flow-It ALC Flowable Composite Syringe Value Pack Shade B1
N11VD	Flow-It ALC Flowable Composite Syringe Value Pack Shade B2
N11VE	Flow-It ALC Flowable Composite Syringe Value Pack Shade B3
N11VM	Flow-It ALC Flowable Composite Syringe Value Pack Shade B4
N11VN	Flow-It ALC Flowable Composite Syringe Value Pack Shade C1
N11VF	Flow-It ALC Flowable Composite Syringe Value Pack Shade A1C2
N11VG	Flow-It ALC Flowable Composite Syringe Value Pack Shade C3
N11VO	Flow-It ALC Flowable Composite Syringe Value Pack Shade C4
N11VH	Flow-It ALC Flowable Composite Syringe Value Pack Shade Clear

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(continued from page 2)

Object(s) of the Declaration: Flow-It ALC
(Class IIa)

Finished Article

<u>Number</u>	<u>Description</u>
N11VP	Flow-It ALC Flowable Composite Syringe Value Pack Shade D2
N11VQ	Flow-It ALC Flowable Composite Syringe Value Pack Shade D3
N11VR	Flow-It ALC Flowable Composite Syringe Value Pack Shade D4
N11VXC	Flow-It ALC Flowable Composite Syringe Value Pack Shade Incisal
N11VU	Flow-It ALC Flowable Composite Syringe Value Pack Shade Pedo Light
N11VV	Flow-It ALC Flowable Composite Syringe Value Pack Shade Extra Light
N11VXD	Flow-It ALC Flowable Composite Syringe Value Pack Shade White Opaque
N11VI	Flow-It ALC Flowable Composite Syringe Value Pack Shade Universal Opaque

PENTRON

EC-Prohlášení o shodě

Název společnosti, která vydává prohlášení: Pentron Clinical

Adresa společnosti: 1717 West Collins Avenue, Orange, CA 92867, USA

Evropský zástupce: SpofaDental a.s., Markova 238, CZ-506 01 Jičín, Česká Republika

Předmět prohlášení: Flow-It ALC
(Třída IIa)

Číslo hotového artiklu Popis

N11WA	Flow-It ALC Flowable Composite Intro Kit
N11XA	Flow-It ALC Flowable Composite Syringe Shade A0
N11A	Flow-It ALC Flowable Composite Syringe Shade A1
N11B	Flow-It ALC Flowable Composite Syringe Shade A2
N11C	Flow-It ALC Flowable Composite Syringe Shade A3
N11J	Flow-It ALC Flowable Composite Syringe Shade A3.5
N11K	Flow-It ALC Flowable Composite Syringe Shade A4
N11XB	Flow-It ALC Flowable Composite Syringe Shade B0
N11L	Flow-It ALC Flowable Composite Syringe Shade B1

(Pokračování na straně 2)

Tímto prohlášením o shodě
Pentron Clinical
potvrzuje a prohlašuje,

že výše uvedené položky patří do třídy výrobků IIa podle Přílohy IX Směrnice 93/42/EEC a jsou vyrobeny v souladu s ustanovením Směrnice Rady 93/42/EEC a technickou dokumentací uvedenou v Příloze VII, Oddíl 3 a v Příloze V ve znění Směrnice 2007/47/EC a proto splňují požadavky Směrnice o prostředcích zdravotnické techniky, jak uvádí certifikát CE 00847, který vydal BSI, Notifikovaná osoba č. 0086. Směrnice 93/42/EEC je implementována v České republice nařízením vlády č. 336/2004 Sb., kterým se stanoví technické požadavky na zdravotnické prostředky, ve znění pozdějších předpisů.

Jméno: Mark Dzendzel

Pozice: Senior Quality Assurance Manager

Podpis:



Datum:

9 March 2015

PENTRON

EC-Prohlášení o shodě

(Pokračování ze strany 1)

Předmět prohlášení: Flow-It ALC

(Třída IIa)

<u>Číslo hotového</u>	<u>Popis</u>
<u>artiklu</u>	
N11D	Flow-It ALC Flowable Composite Syringe Shade B2
N11E	Flow-It ALC Flowable Composite Syringe Shade B3
N11M	Flow-It ALC Flowable Composite Syringe Shade B4
N11N	Flow-It ALC Flowable Composite Syringe Shade C1
N11F	Flow-It ALC Flowable Composite Syringe Shade C2
N11G	Flow-It ALC Flowable Composite Syringe Shade C3
N11O	Flow-It ALC Flowable Composite Syringe Shade C4
N11H	Flow-It ALC Flowable Composite Syringe Shade CLEAR
N11P	Flow-It ALC Flowable Composite Syringe Shade D2
N11Q	Flow-It ALC Flowable Composite Syringe Shade D3
N11R	Flow-It ALC Flowable Composite Syringe Shade D4
N11XC	Flow-It ALC Flowable Composite Syringe Shade Incisal
N11U	Flow-It ALC Flowable Composite Syringe Shade Pedo Light
N11V	Flow-It ALC Flowable Composite Syringe Shade Pedo Extra Light
N11I	Flow-It ALC Flowable Composite Syringe Shade Universal Opaque
N11XD	Flow-It ALC Flowable Composite Syringe Shade White Opaque
N11VXA	Flow-It ALC Flowable Composite Syringe Value Pack Shade A0
N11VA	Flow-It ALC Flowable Composite Syringe Value Pack Shade A1
N11VB	Flow-It ALC Flowable Composite Syringe Value Pack Shade A2
N11VC	Flow-It ALC Flowable Composite Syringe Value Pack Shade A3
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N11VK	Flow-It ALC Flowable Composite Syringe Value Pack Shade A4
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N11VL	Flow-It ALC Flowable Composite Syringe Value Pack Shade B1
N11VD	Flow-It ALC Flowable Composite Syringe Value Pack Shade B2
N11VE	Flow-It ALC Flowable Composite Syringe Value Pack Shade B3
N11VM	Flow-It ALC Flowable Composite Syringe Value Pack Shade B4
N11VN	Flow-It ALC Flowable Composite Syringe Value Pack Shade C1
N11VF	Flow-It ALC Flowable Composite Syringe Value Pack Shade A1C2
N11VG	Flow-It ALC Flowable Composite Syringe Value Pack Shade C3
N11VO	Flow-It ALC Flowable Composite Syringe Value Pack Shade C4
N11VH	Flow-It ALC Flowable Composite Syringe Value Pack Shade Clear

(Pokračování na straně 3)

PENTRON

EC-Prohlášení o shodě

(Pokračování ze strany 2)

Předmět prohlášení: Flow-It ALC
(Třída IIa)

<u>Číslo hotového</u> <u>Artiklu</u>	<u>Popis</u>
N11VP	Flow-It ALC Flowable Composite Syringe Value Pack Shade D2
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N11VU	Flow-It ALC Flowable Composite Syringe Value Pack Shade Pedo Light
N11VV	Flow-It ALC Flowable Composite Syringe Value Pack Shade Extra Light
N11VXD	Flow-It ALC Flowable Composite Syringe Value Pack Shade White Opaque
N11VI	Flow-It ALC Flowable Composite Syringe Value Pack Shade Universal Opaque