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: FibreKleer 4X
(Class IIa)

Finished Article Number	Description
N83A	FibreKleer 4X Parallel Fiber Post Kit
N83B	FibreKleer 4X Tapered Fiber Post Kit
N83C	FibreKleer 4X Original Fiber Post Kit
N83AA	Refill - FibreKleer 4X Post Parallel 1.00mm, 10PK
N83AB	Refill - FibreKleer 4X Post Parallel 1.25mm, 10PK
N83AC	Refill - FibreKleer 4X Post Parallel 1.50mm, 10PK
N83AD	Refill - FibreKleer 4X Post Parallel 1.00mm 30PK
N83AE	Refill - FibreKleer 4X Post Parallel 1.25mm 30PK

(Continued on page 2)

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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EC-Declaration of Conformity

(Continued from page 1)

Object(s) of the Declaration: FibreKleer 4X
(Class IIa)

Finished Article Number	Description
N83AF	Refill - FibreKleer 4X Post Parallel 1.50mm 30PK
N83AT	FibreKleer 4X Post Parallel Trial Kit
N83BA	Refill - FibreKleer 4X Post Tapered 1.25mm 10PK
N83BB	Refill - FibreKleer 4X Post Tapered 1.375mm 10PK
N83BC	Refill - FibreKleer 4X Post Tapered 1.50mm 10PK
N83BD	Refill - FibreKleer 4X Post Tapered 1.25mm 30PK
N83BE	Refill - FibreKleer 4X Post Tapered 1.375mm 30PK
N83BF	Refill - FibreKleer 4X Post Tapered 1.50mm 30PK
N83BT	FibreKleer 4X Post Tapered Trial Kit
N83CA	Refill - FibreKleer 4X Post Original 1.00mm 10PK
N83CB	Refill - FibreKleer 4X Post Original 1.25mm 10PK
N83CC	Refill - FibreKleer 4X Post Original 1.50mm 10PK
N83CD	Refill - FibreKleer 4X Post Original 1.00mm 30PK
N83CE	Refill - FibreKleer 4X Post Original 1.25mm 30PK
N83CF	Refill - FibreKleer 4X Post Original 1.50mm 30PK
N83CT	FibreKleer 4X Post Original Trial Kit

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: FibreKleer 4X
(Třída IIa)

Číslo hotového artiklu	Popis
N83A	FibreKleer 4X Parallel Fiber Post Kit
N83B	FibreKleer 4X Tapered Fiber Post Kit
N83C	FibreKleer 4X Original Fiber Post Kit
N83AA	Refill - FibreKleer 4X Post Parallel 1.00mm, 10PK
N83AB	Refill - FibreKleer 4X Post Parallel 1.25mm, 10PK
N83AC	Refill - FibreKleer 4X Post Parallel 1.50mm, 10PK
N83AD	Refill - FibreKleer 4X Post Parallel 1.00mm 30PK
N83AE	Refill - FibreKleer 4X Post Parallel 1.25mm 30PK
N83AF	Refill - FibreKleer 4X Post Parallel 1.50mm 30PK

(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: FibreKleer 4X
(Třída IIa)

Číslo hotového artiklu	Popis
N83AT	FibreKleer 4X Post Parallel Trial Kit
N83BA	Refill - FibreKleer 4X Post Tapered 1.25mm 10PK
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N83BD	Refill - FibreKleer 4X Post Tapered 1.25mm 30PK
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