BRACCO INJENEERING	EC-DECLARATION OF CONFORMITY

EC DECLARATION OF CONFORMITY N° 480-N-Syringe Pack-V06

We,
Bracco Injeneering
Avenue de Sévelin 46
1004 Lausanne
Switzerland

declare under our own responsibility that the below product meets all the provisions of the European Medical Devices Directive (Council Directive 93/42/EEC of 14 June 1993 concerning medical devices) and applicable transposed laws that applies to the product and therefore we duly attach the CE-marking to it.

The bases for this EC Declaration of the Conformity are the contents of the Technical File for the product, in particular the proof of conformity to the Essential Requirements (MDD, Annex I).

The batch or serial numbers of the devices covered by this EC Declaration of Conformity, as well as the quantity released, are recorded in Bracco Injeneering SA's Quality System.

The validity of this EC Declaration of Conformity is reviewed at Bracco Injeneering SA's Management Review Meeting.

Product description:	**Product code:**
FastLoad™ CT Syringe Pack	017344
FastLoad™ CT Syringe Pack with Spike	017345
FastLoad™ CTA Dual Syringe Pack	017346
FastLoad™ CTA Dual Syringe Pack with Spikes	017347
FastLoad™ CTA Dual Syringe Pack (DCV)	017354
FastLoad™ CTA Dual Syringe Pack with Spikes (DCV)	017355
FastLoad™ MR Syringe Pack	017348
FastLoad™ MR Syringe Pack (DCV)	017356
FastLoad™ MR Single Syringe Pack	640365
Regulatory class (MDD, Annex IX):	class IIa, rule 2
Conformity assessment procedure:	Full quality assurance system (Annex II) excluding the design examination (point four of Annex II)

Notified Body:	BSI Group, Identification number 0086 Kitemark Court, Davy Avenue Milton Keynes MK5 8PP United Kingdom
EC Certificate	CE 598543
EN ISO 13485 Certificate	MD 598569
Place, Date of issue	Lausanne, October 2nd, 2017

Signature :

Michael Edwards
QA/RA Director
BRACCO INJENEERING