

**EC DECLARATION OF CONFORMITY N° 480-N-PL-V12**

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.

<b>Product:</b>	<b>Patient Line</b>
<b>BINJ product code:</b>	640063
<b>Regulatory class (MDD, Annex IX):</b>	class IIa, rule 2
<b>Conformity assessment procedure:</b>	Full quality assurance system, Annex II.3

<b>Notified Body:</b>	BSI Group The Netherlands B.V., Identification number 2797 Say Building John M. Keynesplein 9 1066 EP Amsterdam
<b>EC Certificate</b>	CE 598543
<b>EN ISO 13485 Certificate</b>	MD 598569
<b>Place, Date of issue</b>	Lausanne, March 11 <sup>th</sup> , 2019

Signature :



Wouter Vlaanderen  
 Managing Director  
