

EC DECLARATION OF CONFORMITY N° 480-N-BSA-V14

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:	Bottle Spike A
BINJ product code:	640058 / 640458
Regulatory class (MDD, Annex IX):	class IIa, rule 2
Conformity assessment procedure:	Full quality assurance system, Annex II.3

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

Signature :



Wouter Vlaanderen
 Managing Director
