

EC DECLARATION OF CONFORMITY N° 480-N-CT4D-V08

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:	CT ExpresTM 4D
BINJ product code:	650208 / 1056543
Regulatory class (MDD, Annex IX):	class IIb, rule 11
Conformity assessment procedure:	Full quality assurance system, Annex II.3

The main applied harmonized standards, national standards or other normative documents are the following (this list is not exhaustive, refers to the product Essential Requirements checklist):

Electrical safety and essential performance:	EN 60601-1:2006 EN 60601-1-2:2007 EN 60601-1-8:2007 EN 60601-2-24:1998
Software:	EN 62304:2006
Usability:	EN 62366:2008
Labelling:	EN ISO 15223-1:2012 EN 15986:2011
QMS:	EN ISO 13485:2012
Risk management:	EN ISO 14971:2012

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, August 06 2013

Signature :



Marc Gingins
Quality & RA Director
Site Manager
**BRACCO
INJENEERING**