ACIST Medical Systems, Inc.
A BRACCO COMPANY

DECLARATION OF CONFORMITY

Legal Manufacturer Name and Address	**European Authorized Representative and Address**
ACIST Medical Systems, Inc. 7905 Fuller Road Eden Prairie, Minnesota 55344 USA	Medical Product Service GmbH Borngasse 20 35619 Braunfels, Germany

Product Name:	ACIST CVi™ Contrast Delivery Disposable Kits
Model Names & SKUs:	A2000 Multi use Syringe Kit, 014612 A2000V Multi use Syringe Kit, 014113 BT2000 Automated Manifold Kit With Transducer, 014613 AngioTouch AT P54 Hand Controller Kit, 014644 AngioTouch AT P65 Hand Controller Kit, 014645
Declaration:	The product listed herein is under the sole responsibility of ACIST Medical Systems. The product(s) listed above are in conformity to essential requirements (Annex I) of the Council Directive 93/42/EEC, as amended by 2007/47/EC concerning Medical Devices & applicable transposed laws.
Classification:	The ACIST CVi™ Contrast Delivery Disposable Kits as listed above are Class IIa per Annex IX, Rule 2, first bullet of the Medical Device Directive 93/42/EEC.
Conformity Assessment Route:	EC Declaration of Conformity via a full quality assurance system (Annex II) excluding the design examination (point four of Annex II).
Notified Body:	BSI, Identification Number 2797
EC Certificate for Full Quality Assurance:	CE 66263
Quality Management Systems Certificate:	FM 76043
Place and Date of Issue:	Eden Prairie, Minnesota, USA; 01-June-2020

Signature:

Jennifer Ruether, Senior Manager, Regulatory Affairs
ACIST Medical Systems, Inc.

CONFIDENTIAL

Signed by /
Podpisano przez:

Aleksandra
Natalia Siedlecka

Date / Data:
2022-11-15 12:22

Revision History			
Revision	**Prepared By**	**Date**	**Revision Description**
01	Melissa Sommerfeld	02/27/2019	Initial Release under controlled form DoC0130 for BSI Identification Number 2797.
02	Subbaram Reddy Nyarati	04/25/2019	Updated QMS ISO 13485 Certificate to the correct reference.
03	Jeff Koll	06/01/2020	Periodic update.