

Siemens Healthineers AG, SHS AT QT, Siemensstr. 1, 91301 Forchheim, Germany

Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752
USA

Name	Dr. Christian Denger
Department	Head of Quality
E-Mail	Christian.denger@siemens-healthineers.com
Date	09.04.2024

Confirmation of Compatibility (CoC)

Ladies and gentlemen,

We, as responsible individuals authorized to represent and act on behalf of Siemens Healthcare GmbH, Henkestr. 127, 91052 Erlangen, Germany hereby declares the Confirmation of Compatability (CoC) regarding the Boston Scientific combinations with products of Artis family including current restrictions in the attachments.

Sincerely yours,

Siemens Healthcare GmbH

i.v. Denger

Electronically signed by:
Christian Denger
Reason: I am approving this
document
Date: Apr 10, 2024 17:04 GMT+2

Dr. Christian Denger
Head of Quality
Business Area Advanced Therapies

i.v. Ali-Ihsan Can

Electronically signed by: Ali-
Ihsan Can
Reason: I am approving this
document
Date: Apr 9, 2024 17:04 GMT+2

Ali-Ihsan Can
Head of Regulatory Clinical Affairs
Business Area Advanced Therapies

Siemens Healthineers AG
Chairman of the Supervisory Board: Ralf P. Thomas;
Managing Board: Bernhard Montag, President and Chief Executive Officer;
Members of the Managing Board: Darleen Caron, Jochen Schmitz,
Elisabeth Staudinger-Leibrecht

Registered office: Munich, Germany; Commercial Registry: Munich, HRB 237558;
WEEE-Reg.-No. DE 64872105

Confirmation of Compatibility Artis – Avvigo+

Siemensstr. 1
91301 Forchheim
Germany

Tel.: +49 9191 18 0
Fax: +49 9191 18 9999
siemens-healthineers.com

Product identification Artis VC/VD

Main medical device (MDR)	Model	UDI-DI	UDI-PI	Version
Artis zee floor	10094135	04056869010045	From: 139000	VD12
Artis zee ceiling	10094137	04056869010052	From: 150000	VD12
Artis zee multi-purpose	10094139	04056869010076	From: 159000	VD12
Artis zee biplane	10094141	04056869010069	From: 156000	VD12
Artis Q floor	10848280	04056869009971	From: 104000	VD12
Artis Q ceiling	10848281	04056869009988	From: 110000	VD12
Artis Q biplane	10848282	04056869009995	From: 122000	VD12
Artis Q.zen floor	10848353	04056869010014	From: 105500	VD12
Artis Q.zen ceiling	10848354	04056869010021	From: 111500	VD12
Artis Q.zen biplane	10848355	04056869010038	From: 123500	VD12
Artis zeego	10280959	04056869010083	n.a.	VD12 upgrade
Artis zeego (Q technology)	10848283	04056869010007	n.a.	VD12 upgrade
Artis zeego III	10502505	04056869012681	n.a.	VD1x
Artis zee III floor	10502501	04056869012643	From: 101000	VD12
Artis zee III ceiling	10502502	04056869012650	From: 107000	VD12
Artis zee III biplane	10502504	04056869012674	From: 120500	VD12

Manufacturer	Product	Identification (3rd party manufacturer)	UDI-DI / GTIN	Class of MD (MDD / MDR*)	CE marking (MDR*)	Artis zee VD1x / VC21					Artis Q VD1x				Artis Q.zen VD1x			Restriction
						floor	ceiling	biplane	MP	zeego	floor	ceiling	biplane	zeego	floor	ceiling	biplane	
Boston Scientific	AVVIGO+™ Multi- Modality Guidance System Mobile, US	H7492493120C0	n.a.	Ila (acc. to 510k)	n.a.	•	•	•		•	•	•	•	•	•	•	•	
	AVVIGO+™ Multi- Modality Guidance System Integrated , US	H7492493120I0	n.a.	Ila (acc. to 510k)	n.a.	•	•	•		•	•	•	•	•	•	•	•	#
	MDU – Fast pullback S/N (Avvigo+)	H749MDU5PLUSF 0	n.a.	Ila (acc. to 510k)	n.a.	•	•	•		•	•	•	•	•	•	•	•	
	FFR Link	H7495551000	n.a.	Ila (acc. to 510k)	n.a.	•	•	•		•	•	•	•	•	•	•	•	

Table : List of product combinations with Artis VC/VD family.

Restrictions Artis VC/VD:

	Avvigo II mobile Avvigo+ mobile	Avvigo II integrated, Avvigo+ integrated floor mount	AVVIGO+ integrated boom-mount
Artis zee/Q/Q.zen VD1x	•	•	Not released

Product identification Artis VE

Main medical device	Model	UDI-DI	UDI-PI	Version
ARTIS icono floor	11327700	04056869149325	170000 onwards	VE2x / VE3x
ARTIS icono biplane	11327600	04056869063317	180000 onwards	VE2x / VE3x
ARTIS icono ceiling	11328100	04056869295923	190000 onwards	VE23
ARTIS pheno	10849000	04056869046877	164600 onwards	VE2x / VE3x
ARTIS pheno	10849000	04056869046877	164162 to 164599	VE1x / VE3x

Manufacturer	Product	Identification (3rd party manufacturer)	UDI-DI / GTIN	Class of MD (MDD / MDR*)	CE marking (MDR*)	ARTIS pheno			ARTIS icono floor		ARTIS icono biplane		ARTIS icono ceiling	Restriction VE
						VE1 x	VE2 x	VE3 x	VE2 x	VE3 x	VE2 x	VE3 x	VE2 3	
Boston Scientific	AVVIGO+™ Multi-Modality Guidance System Mobile, US	H7492493120C0	n.a.	Ila (acc. to 510k)	n.a.	•	•	•	•	•	•	•	•	
	AVVIGO+™ Multi-Modality Guidance System Integrated, US	H7492493120I0	n.a.	Ila (acc. to 510k)	n.a.	•	•	•	•	•	•	•	•	#
	MDU - Fast pullback S/N (Avvigo+)	H749MDU5PLUSF0	n.a.	Ila (acc. to 510k)	n.a.	•	•	•	•	•	•	•	•	
	FFR Link	H7495551000	n.a.	Ila (acc. to 510k)	n.a.	•	•	•	•	•	•	•	•	

Table: List of product combinations with Artis VE family.

Restrictions Artis VE:

	Avvigo II mobile Avvigo+ mobile	Avvigo II integrated, Avvigo+ integrated floor mount	AVVIGO+ integrated boom-mount
Artis icono/pheno VE1x, VE2x, VE3x	•	Not released	•

1. The combination between Avvigo Guidance System II and AVVIGO+™ Multi-Modality Guidance System as integrated floor mount versions with the Artis VE systems (VE1x, VE2x, VE3x) is not released.
2. The DCS integration for ARTIS VExy systems is part of this combination review but as upgrade setup and for following DCS variants only: DCS movable LD 10848867, DCS fix LD 10848863, DCS moveable for Biplane 11327743. (Hint: Boom mount setup is not released for DCS variants for 2x32 (10848866, 11327744, 10848861) and DCS-fix XL (30000193)).
3. The boom mount (DCS) solution for ARTIS pheno/icono systems is released conditionally.
4. The combined boom mount solution of Acuson Freestyle Ultrasound System and AVVIGO+ is not released.
5. Pre-routing of the BSci Avvigo+ cables in AT factory or during initial Artis system setup is not yet released.