

# EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices, Annex II Section 4

**No.****CE 650110****Issued To:**

**Shanghai Shape Memory Alloy  
Co., Ltd.  
1F and 5F, Tower 41  
No. 258 XinZhuan Road  
Songjiang High-Tech Park  
CaoHeJing Development District  
Shanghai  
201612  
China**

**In respect of:**

**MemoPart™ ASD, PDA, VSD, PFO, Plug Occluders and related Delivery Systems.  
MemoPart™ Snares.**

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Gary E Slack, Senior Vice President Medical Devices

**First Issued: 2016-11-24****Date: 2020-06-03****Expiry Date: 2021-11-23**

...making excellence a habit.™

Page 1 of 33

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

# EC Design-Examination Certificate

## Supplementary Information to CE 650110

Issued To:

**Shanghai Shape Memory Alloy  
Co., Ltd.  
1F and 5F, Tower 41  
No. 258 XinZhuan Road  
Songjiang High-Tech Park  
CaoHeJing Development District  
Shanghai  
201612  
China**

**Device name: MemoPart™ ASD Occluder**

**Intended purpose per IFU:** The MemoPart™ ASD Occluder is a percutaneous, transcatheter, atrial septal defect closure device intended for the occlusion of atrial septal defects (ASD) in secundum position or patients who have undergone a fenestrated Fontan procedure and who require closure of the fenestration. Patients indicated for ASD closure have echocardiographic evidence of ostium secundum atrial septal defect and clinical evidence of right ventricular volume overload.

**Classification:** Class III Implant

Catalogue No	Model, type				
	Connecting waist OD (mm)	Connecting waist height (mm)	LA Disc OD (mm)	RA Disc OD (mm)	Smallest recommended Sheath
FQFDQ-I06	6.0±0.5	5.5±0.5	16.0±1.0	14.0±1.0	8-9F
FQFDQ-I07	7.0±0.5	5.5±0.5	21.0±1.0	17.0±1.0	8-9F
FQFDQ-I08	8.0±0.5	5.5±0.5	18.0±1.0	16.0±1.0	8-9F
FQFDQ-I09	9.0±0.5	5.5±0.5	23.0±1.0	19.0±1.0	8-9F
FQFDQ-I10	10.0±0.5	5.5±0.5	20.0±1.0	18.0±1.0	9-10F
FQFDQ-I11	11.0±0.6	5.5±0.75	25.0±1.25	21.0±1.25	9-10F
FQFDQ-I12	12.0±0.6	5.5±0.75	22.0±1.25	20.0±1.25	9-10F
FQFDQ-I13	13.0±0.6	5.5±0.75	27.0±1.25	23.0±1.25	9-10F
FQFDQ-I14	14.0±0.6	5.5±0.75	24.0±1.25	22.0±1.25	9-10F
FQFDQ-I15	15.0±0.6	5.5±0.75	29.0±1.25	25.0±1.25	9-10F
FQFDQ-I16	16.0±0.6	5.5±0.75	30.0±1.5	26.0±1.25	10-12F
FQFDQ-I17	17.0±0.75	5.5±0.75	31.0±1.5	27.0±1.25	10-12F
FQFDQ-I18	18.0±0.75	5.5±0.75	32.0±1.5	28.0±1.5	10-12F
FQFDQ-I19	19.0±0.75	5.5±0.75	33.0±1.5	29.0±1.5	10-12F

First Issued: **2016-11-24**

Date: **2020-06-03**

Expiry Date: **2021-11-23**

...making excellence a habit.™

Page 2 of 33

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

# EC Design-Examination Certificate

## Supplementary Information to CE 650110

Issued To:

**Shanghai Shape Memory Alloy  
Co., Ltd.  
1F and 5F, Tower 41  
No. 258 XinZhuan Road  
Songjiang High-Tech Park  
CaoHeJing Development District  
Shanghai  
201612  
China**

**Device name: MemoPart™ ASD Occluder**

**Intended purpose per IFU:** The MemoPart™ ASD Occluder is a percutaneous, transcatheter, atrial septal defect closure device intended for the occlusion of atrial septal defects (ASD) in secundum position or patients who have undergone a fenestrated Fontan procedure and who require closure of the fenestration. Patients indicated for ASD closure have echocardiographic evidence of ostium secundum atrial septal defect and clinical evidence of right ventricular volume overload.

**Classification:** Class III Implant

Catalogue No	Model, type				
	Connecting waist OD (mm)	Connecting waist height (mm)	LA Disc OD (mm)	RA Disc OD (mm)	Smallest recommended Sheath
FQFDQ-I20	20.0±0.75	5.5±0.75	34.0±1.5	30.0±1.5	10-12F
FQFDQ-I22	22.0±1.0	5.5±1.0	36.0±1.75	32.0±1.75	10-12F
FQFDQ-I24	24.0±1.0	5.5±1.0	38.0±1.75	34.0±1.75	12-14F
FQFDQ-I26	26.0±1.0	5.5±1.0	40.0±1.75	36.0±1.75	12-14F
FQFDQ-I28	28.0±1.0	5.5±1.0	42.0±1.75	38.0±1.75	12-14F
FQFDQ-I30	30.0±1.0	5.5±1.0	44.0±1.75	40.0±1.75	14F
FQFDQ-I32	32.0±1.0	5.5±1.0	47.0±1.75	42.0±1.75	14F
FQFDQ-I34	34.0±1.0	5.5±1.0	49.0±1.75	44.0±1.75	14F
FQFDQ-I36	36.0±1.0	5.5±1.0	51.0±1.75	46.0±1.75	14F
FQFDQ-I38	38.0±1.0	5.5±1.0	54.0±1.75	50.0±1.75	14F
FQFDQ-I40	40.0±1.0	5.5±1.0	56.0±1.75	52.0±1.75	14F
FQFDQ-I42	42.0±1.0	5.5±1.0	58.0±1.75	54.0±1.75	14F
FQFDQ-I44	44.0±1.0	5.5±1.0	60.0±1.75	56.0±1.75	14F
FQFDQ-I46	46.0±1.0	5.5±1.0	62.0±1.75	58.0±1.75	14F
FQFDQ-I48	48.0±1.0	5.5±1.0	64.0±1.75	60.0±1.75	14F
FQFDQ-I50	50.0±1.0	5.5±1.0	66.0±1.75	62.0±1.75	14F

First Issued: **2016-11-24**

Date: **2020-06-03**

Expiry Date: **2021-11-23**

...making excellence a habit.™

Page 3 of 33

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

# EC Design-Examination Certificate

## Supplementary Information to CE 650110

Issued To:

**Shanghai Shape Memory Alloy  
Co., Ltd.  
1F and 5F, Tower 41  
No. 258 XinZhuan Road  
Songjiang High-Tech Park  
CaoHeJing Development District  
Shanghai  
201612  
China**

**Device name: MemoPart™ ASD Occluder**

**Intended purpose per IFU:** The MemoPart™ ASD Occluder is a percutaneous, transcatheter, atrial septal defect closure device intended for the occlusion of atrial septal defects (ASD) in secundum position or patients who have undergone a fenestrated Fontan procedure and who require closure of the fenestration. Patients indicated for ASD closure have echocardiographic evidence of ostium secundum atrial septal defect and clinical evidence of right ventricular volume overload.

**Classification:** Class III Implant

Catalogue No	Model, type				
	Connecting waist OD (mm)	Connecting waist height (mm)	LA Disc OD (mm)	RA Disc OD (mm)	Smallest recommended Sheath
WTFQFDQ-I06	6.0±0.5	5.5±0.5	16.0±1.0	14.0±1.0	8-9F
WTFQFDQ-I07	7.0±0.5	5.5±0.5	21.0±1.0	17.0±1.0	8-9F
WTFQFDQ-I08	8.0±0.5	5.5±0.5	18.0±1.0	16.0±1.0	8-9F
WTFQFDQ-I09	9.0±0.5	5.5±0.5	23.0±1.0	19.0±1.0	8-9F
WTFQFDQ-I10	10.0±0.5	5.5±0.5	20.0±1.0	18.0±1.0	9-10F
WTFQFDQ-I11	11.0±0.6	5.5±0.75	25.0±1.5	21.0±1.25	9-10F
WTFQFDQ-I12	12.0±0.6	5.5±0.75	22.0±1.25	20.0±1.25	9-10F
WTFQFDQ-I13	13.0±0.6	5.5±0.75	27.0±1.25	23.0±1.25	9-10F
WTFQFDQ-I14	14.0±0.6	5.5±0.75	24.0±1.25	22.0±1.25	9-10F
WTFQFDQ-I15	15.0±0.6	5.5±0.75	29.0±1.25	25.0±1.25	9-10F
WTFQFDQ-I16	16.0±0.6	5.5±0.75	30.0±1.5	26.0±1.25	10-12F
WTFQFDQ-I17	17.0±0.75	5.5±0.75	31.0±1.5	27.0±1.25	10-12F
WTFQFDQ-I18	18.0±0.75	5.5±0.75	32.0±1.5	28.0±1.5	10-12F
WTFQFDQ-I19	19.0±0.75	5.5±0.75	33.0±1.5	29.0±1.5	10-12F
WTFQFDQ-I20	20.0±0.75	5.5±0.75	34.0±1.5	30.0±1.5	10-12F

First Issued: **2016-11-24**

Date: **2020-06-03**

Expiry Date: **2021-11-23**

...making excellence a habit.™

Page 4 of 33

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.



# EC Design-Examination Certificate

## Supplementary Information to CE 650110

Issued To:

**Shanghai Shape Memory Alloy  
Co., Ltd.  
1F and 5F, Tower 41  
No. 258 XinZhuan Road  
Songjiang High-Tech Park  
CaoHeJing Development District  
Shanghai  
201612  
China**

**Device name: MemoPart™ ASD Occluder**

**Intended purpose per IFU:** The MemoPart™ ASD Occluder is a percutaneous, transcatheter, atrial septal defect closure device intended for the occlusion of atrial septal defects (ASD) in secundum position or patients who have undergone a fenestrated Fontan procedure and who require closure of the fenestration. Patients indicated for ASD closure have echocardiographic evidence of ostium secundum atrial septal defect and clinical evidence of right ventricular volume overload.

**Classification:** Class III Implant

Catalogue No	Model, type				
	Connecting waist OD (mm)	Connecting waist height (mm)	LA Disc OD (mm)	RA Disc OD (mm)	Smallest recommended Sheath
WTFQFDQ-I22	20.0±1.0	5.5±1.0	36.0±1.75	32.0±1.75	10-12F
WTFQFDQ-I24	24.0±1.0	5.5±1.0	38.0±1.75	34.0±1.75	12-14F
WTFQFDQ-I26	26.0±1.0	5.5±1.0	40.0±1.75	36.0±1.75	12-14F
WTFQFDQ-I28	28.0±1.0	5.5±1.0	42.0±1.75	38.0±1.75	12-14F
WTFQFDQ-I30	30.0±1.0	5.5±1.0	44.0±1.75	40.0±1.75	14F
WTFQFDQ-I32	32.0±1.0	5.5±1.0	48.0±1.75	42.0±1.75	14F
WTFQFDQ-I34	34.0±1.0	5.5±1.0	50.0±1.75	44.0±1.75	14F
WTFQFDQ-I36	36.0±1.0	5.5±1.0	52.0±1.75	46.0±1.75	14F
WTFQFDQ-I38	38.0±1.0	5.5±1.0	54.0±1.75	50.0±1.75	14F
WTFQFDQ-I40	40.0±1.0	5.5±1.0	56.0±1.75	52.0±1.75	14F
WTFQFDQ-I42	42.0±1.0	5.5±1.0	58.0±1.75	54.0±1.75	14F
WTFQFDQ-I44	44.0±1.0	5.5±1.0	60.0±1.75	56.0±1.75	14F
WTFQFDQ-I46	46.0±1.0	5.5±1.0	62.0±1.75	58.0±1.75	14F
WTFQFDQ-I48	48.0±1.0	5.5±1.0	64.0±1.75	60.0±1.75	14F
WTFQFDQ-I50	50.0±1.0	5.5±1.0	66.0±1.75	62.0±1.75	14F

First Issued: **2016-11-24**

Date: **2020-06-03**

Expiry Date: **2021-11-23**

...making excellence a habit.™

Page 5 of 33

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

# EC Design-Examination Certificate

## Supplementary Information to CE 650110

Issued To:

**Shanghai Shape Memory Alloy  
Co., Ltd.  
1F and 5F, Tower 41  
No. 258 XinZhuan Road  
Songjiang High-Tech Park  
CaoHeJing Development District  
Shanghai  
201612  
China**

**Device name: MemoPart™ ASD Occluder**

**Intended purpose per IFU:** The MemoPart™ ASD Occluder is a percutaneous, transcatheter, atrial septal defect closure device intended for the occlusion of atrial septal defects (ASD) in secundum position or patients who have undergone a fenestrated Fontan procedure and who require closure of the fenestration. Patients indicated for ASD closure have echocardiographic evidence of ostium secundum atrial septal defect and clinical evidence of right ventricular volume overload.

**Classification:** Class III Implant

Catalogue No	Model, type				
	Connecting waist OD (mm)	Connecting waist height (mm)	LA Disc OD (mm)	RA Disc OD (mm)	Smallest recommended Sheath
FQFDQ-II06	6±0.75	5.5±0.5	30±1.5	22±1.5	9-10F
FQFDQ-II08	8±0.75	5.5±0.5	32±1.5	24±1.5	9-10F
FQFDQ-II10	10±0.75	5.5±0.5	34±1.5	26±1.5	10-12F
FQFDQ-II12	12±0.75	5.5±0.5	36±1.5	28±1.5	10-12F
FQFDQ-II14	14±0.75	5.5±0.5	38±1.5	30±1.5	10-12F
FQFDQ-II16	16±0.75	5.5±0.75	40±1.5	32±1.5	12-14F
FQFDQ-II18	18±0.75	5.5±0.75	42±1.5	34±1.5	12-14F
FQFDQ-II20	20±0.75	5.5±0.75	44±1.5	36±1.5	12-14F

First Issued: **2016-11-24**

Date: **2020-06-03**

Expiry Date: **2021-11-23**

...making excellence a habit.™

Page 6 of 33

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

# EC Design-Examination Certificate

## Supplementary Information to CE 650110

Issued To:

**Shanghai Shape Memory Alloy  
Co., Ltd.  
1F and 5F, Tower 41  
No. 258 XinZhuan Road  
Songjiang High-Tech Park  
CaoHeJing Development District  
Shanghai  
201612  
China**

**Device name: MemoPart™ ASD Occluder**

**Intended purpose per IFU:** The MemoPart™ ASD Occluder is a percutaneous, transcatheter, atrial septal defect closure device intended for the occlusion of atrial septal defects (ASD) in secundum position or patients who have undergone a fenestrated Fontan procedure and who require closure of the fenestration. Patients indicated for ASD closure have echocardiographic evidence of ostium secundum atrial septal defect and clinical evidence of right ventricular volume overload.

**Classification:** Class III Implant

Catalogue No	Model, type				
	Connecting waist OD (mm)	Connecting waist height (mm)	LA Disc OD (mm)	RA Disc OD (mm)	Smallest recommended Sheath
FQFDQ-II22	22±0.75	5.5±0.75	46±1.5	38±1.5	12-14F
FQFDQ-II24	24±0.75	5.5±0.75	48±1.5	40±1.5	14F
WTFQFDQ-II06	6±0.75	5.5±0.5	30±1.5	22±1.5	9-10F
WTFQFDQ-II08	8±0.75	5.5±0.5	32±1.5	24±1.5	9-10F
WTFQFDQ-II10	10±0.75	5.5±0.5	34±1.5	26±1.5	10-12F
WTFQFDQ-II12	12±0.75	5.5±0.5	36±1.5	28±1.5	10-12F
WTFQFDQ-II14	14±0.75	5.5±0.5	38±1.5	30±1.5	10-12F
WTFQFDQ-II16	16±0.75	5.5±0.75	40±1.5	32±1.5	12-14F
WTFQFDQ-II18	18±0.75	5.5±0.75	42±1.5	34±1.5	12-14F
WTFQFDQ-II20	20±0.75	5.5±0.75	44±1.5	36±1.5	12-14F
WTFQFDQ-II22	22±0.75	5.5±0.75	46±1.5	38±1.5	12-14F
WTFQFDQ-II24	24±0.75	5.5±0.75	48±1.5	40±1.5	14F

First Issued: **2016-11-24**

Date: **2020-06-03**

Expiry Date: **2021-11-23**

...making excellence a habit.™

Page 7 of 33

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

# EC Design-Examination Certificate

## Supplementary Information to CE 650110

Issued To:

**Shanghai Shape Memory Alloy  
Co., Ltd.  
1F and 5F, Tower 41  
No. 258 XinZhuan Road  
Songjiang High-Tech Park  
CaoHeJing Development District  
Shanghai  
201612  
China**

**Device name: MemoPart™ VSD Occluder**

**Intended purpose per IFU:** The MemoPart™ Membranous VSD Occluder is used for minimally invasive transcatheter closure of perimembranous ventricular septal defects.

The MemoPart™ Muscular VSD Occluder is indicated for use in patients with a complex ventricular septal defect (VSD) of significant size to warrant closure (large volume left-to-right shunt, pulmonary hypertension, and/or clinical symptoms of congestive heart failure) who are considered to be at high risk for standard transatrial or transarterial surgical closure based on anatomical conditions and/or based on overall medical condition.

**Classification:** Class III Implant

Catalogue No	Model, type				
	LV Disc OD (mm)	Connecting waist height (mm)	Connecting waist OD (mm)	RV Disc OD (mm)	Smallest recommended Sheath
SQFDQ-Ia04	8.0±1.0	5.0±1.5	4.0±1.0	8.0±1.0	7-8F
SQFDQ-Ia05	9.0±1.0	5.0±1.5	5.0±1.0	9.0±1.0	7-8F
SQFDQ-Ia06	10.0±1.0	5.0±1.5	6.0±1.0	10.0±1.0	8-9F
SQFDQ-Ia07	11.0±1.0	5.0±1.5	7.0±1.0	11.0±1.0	8-9F
SQFDQ-Ia08	12.0±1.0	5.0±1.5	8.0±1.0	12.0±1.0	8-9F
SQFDQ-Ia09	13.0±1.0	5.0±1.8	9.0±1.0	13.0±1.0	8-9F
SQFDQ-Ia10	14.0±1.0	5.0±1.8	10.0±1.2	14.0±1.0	9-10F
SQFDQ-Ia12	16.0±1.0	5.0±1.8	12.0±1.2	16.0±1.0	9-10F
SQFDQ-Ia14	18.0±1.0	5.0±1.8	14.0±1.5	18.0±1.0	10-12F
SQFDQ-Ia16	20.0±1.0	5.0±1.8	16.0±1.5	20.0±1.0	10-12F
SQFDQ-Ia18	22.0±1.0	5.0±1.8	18.0±1.5	22.0±1.0	10-12F
SQFDQ-Ib04	10.0±1.0	7.0±1.5	4.0±1.0	8.0±1.0	7-8F
SQFDQ-Ib05	11.0±1.0	7.0±1.5	5.0±1.0	9.0±1.0	7-8F
SQFDQ-Ib06	12.0±1.0	7.0±1.5	6.0±1.0	10.0±1.0	8-9F
SQFDQ-Ib07	13.0±1.0	7.0±1.5	7.0±1.0	11.0±1.0	8-9F
SQFDQ-Ib08	14.0±1.0	7.0±1.5	8.0±1.0	12.0±1.0	8-9F
SQFDQ-Ib09	15.0±1.0	7.0±1.8	9.0±1.0	13.0±1.0	8-9F

First Issued: **2016-11-24**

Date: **2020-06-03**

Expiry Date: **2021-11-23**

...making excellence a habit.™

Page 8 of 33

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

# EC Design-Examination Certificate

## Supplementary Information to CE 650110

Issued To:

**Shanghai Shape Memory Alloy  
Co., Ltd.  
1F and 5F, Tower 41  
No. 258 XinZhuan Road  
Songjiang High-Tech Park  
CaoHeJing Development District  
Shanghai  
201612  
China**

**Device name: MemoPart™ VSD Occluder**

**Intended purpose per IFU:** The MemoPart™ Membranous VSD Occluder is used for minimally invasive transcatheter closure of perimembranous ventricular septal defects.

The MemoPart™ Muscular VSD Occluder is indicated for use in patients with a complex ventricular septal defect (VSD) of significant size to warrant closure (large volume left-to-right shunt, pulmonary hypertension, and/or clinical symptoms of congestive heart failure) who are considered to be at high risk for standard transatrial or transarterial surgical closure based on anatomical conditions and/or based on overall medical condition.

**Classification:** Class III Implant

Catalogue No	Model, type				
	LV Disc OD (mm)	Connecting waist height (mm)	Connecting waist OD (mm)	RV Disc OD (mm)	Smallest recommended Sheath
SQFDQ- Ib10	16.0±1.0	7.0±1.8	10.0±1.2	14.0±1.0	9-10F
SQFDQ-Ib12	18.0±1.0	7.0±1.8	12.0±1.2	16.0±1.0	9-10F
SQFDQ-Ib14	20.0±1.0	7.0±1.8	14.0±1.5	18.0±1.0	10-12F
SQFDQ-Ib16	22.0±1.0	7.0±1.8	16.0±1.5	20.0±1.0	10-12F
SQFDQ-Ib18	24.0±1.0	7.0±1.8	18.0±1.5	22.0±1.0	10-12F
SQFDQ-Ic04	14.0±1.0	10.0±1.5	4.0±1.0	10.0±1.0	7-8F
SQFDQ-Ic05	15.0±1.0	10.0±1.5	5.0±1.0	11.0±1.0	7-8F
SQFDQ-Ic06	16.0±1.0	10.0±1.5	6.0±1.0	12.0±1.0	8-9F
SQFDQ-Ic07	17.0±1.0	10.0±1.5	7.0±1.0	13.0±1.0	8-9F
SQFDQ-Ic08	18.0±1.0	10.0±1.5	8.0±1.0	14.0±1.0	8-9F
SQFDQ-Ic09	19.0±1.0	10.0±1.8	9.0±1.0	15.0±1.0	8-9F
SQFDQ-Ic10	20.0±1.0	10.0±1.8	10.0±1.2	16.0±1.0	9-10F
SQFDQ-Ic12	22.0±1.0	10.0±1.8	12.0±1.2	18.0±1.0	9-10F
SQFDQ-Ic14	24.0±1.0	10.0±1.8	14.0±1.5	20.0±1.0	10-12F

First Issued: **2016-11-24**

Date: **2020-06-03**

Expiry Date: **2021-11-23**

...making excellence a habit.™

Page 9 of 33

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.



# EC Design-Examination Certificate

## Supplementary Information to CE 650110

Issued To:

**Shanghai Shape Memory Alloy  
Co., Ltd.  
1F and 5F, Tower 41  
No. 258 XinZhuan Road  
Songjiang High-Tech Park  
CaoHeJing Development District  
Shanghai  
201612  
China**

**Device name: MemoPart™ VSD Occluder**

**Intended purpose per IFU:** The MemoPart™ Membranous VSD Occluder is used for minimally invasive transcatheter closure of perimembranous ventricular septal defects.

The MemoPart™ Muscular VSD Occluder is indicated for use in patients with a complex ventricular septal defect (VSD) of significant size to warrant closure (large volume left-to-right shunt, pulmonary hypertension, and/or clinical symptoms of congestive heart failure) who are considered to be at high risk for standard transatrial or transarterial surgical closure based on anatomical conditions and/or based on overall medical condition.

**Classification:** Class III Implant

Catalogue No	Model, type				
	LV Disc OD (mm)	Connecting waist height (mm)	Connecting waist OD (mm)	RV Disc OD (mm)	Smallest recommended Sheath
SQFDQ-Ic16	26.0±1.0	10.0±1.8	16.0±1.5	22.0±1.0	10-12F
SQFDQ-Ic18	28.0±1.0	10.0±1.8	18.0±1.5	24.0±1.0	10-12F
SQFDQ-Id04	18.0±1.0	10.0±1.5	4.0±1.0	10.0±1.0	7-8F
SQFDQ-Id05	19.0±1.0	10.0±1.5	5.0±1.0	11.0±1.0	7-8F

First Issued: **2016-11-24**

Date: **2020-06-03**

Expiry Date: **2021-11-23**

...making excellence a habit.™

Page 10 of 33

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

# EC Design-Examination Certificate

## Supplementary Information to CE 650110

Issued To:

**Shanghai Shape Memory Alloy  
Co., Ltd.  
1F and 5F, Tower 41  
No. 258 XinZhuan Road  
Songjiang High-Tech Park  
CaoHeJing Development District  
Shanghai  
201612  
China**

**Device name: MemoPart™ VSD Occluder**

**Intended purpose per IFU:** The MemoPart™ Membranous VSD Occluder is used for minimally invasive transcatheter closure of perimembranous ventricular septal defects.

The MemoPart™ Muscular VSD Occluder is indicated for use in patients with a complex ventricular septal defect (VSD) of significant size to warrant closure (large volume left-to-right shunt, pulmonary hypertension, and/or clinical symptoms of congestive heart failure) who are considered to be at high risk for standard transatrial or transarterial surgical closure based on anatomical conditions and/or based on overall medical condition.

**Classification:** Class III Implant

Catalogue No	Model, type				
	LV Disc OD (mm)	Connecting waist height (mm)	Connecting waist OD (mm)	RV Disc OD (mm)	Smallest recommended Sheath
SQFDQ-Id06	20.0±1.0	10.0±1.5	6.0±1.0	12.0±1.0	8-9F
SQFDQ-Id07	21.0±1.0	10.0±1.5	7.0±1.0	13.0±1.0	8-9F
SQFDQ-Id08	22.0±1.0	10.0±1.5	8.0±1.0	14.0±1.0	8-9F
SQFDQ-Id09	23.0±1.0	10.0±1.8	9.0±1.0	15.0±1.0	8-9F
SQFDQ-Id10	24.0±1.0	10.0±1.8	10.0±1.2	16.0±1.0	9-10F
SQFDQ-Id12	26.0±1.0	10.0±1.8	12.0±1.2	18.0±1.0	9-10F
SQFDQ-Id14	28.0±1.0	10.0±1.8	14.0±1.5	20.0±1.0	10-12F
SQFDQ-Id16	30.0±1.0	10.0±1.8	16.0±1.5	22.0±1.0	10-12F
SQFDQ-Id18	32.0±1.0	10.0±1.8	18.0±1.5	24.0±1.0	10-12F
WTSQFDQ-Ia04	8.0±1.0	5.0±1.5	4.0±1.0	8.0±1.0	7-8F
WTSQFDQ-Ia05	9.0±1.0	5.0±1.5	5.0±1.0	9.0±1.0	7-8F
WTSQFDQ-Ia06	10.0±1.0	5.0±1.5	6.0±1.0	10.0±1.0	8-9F
WTSQFDQ-Ia07	11.0±1.0	5.0±1.5	7.0±1.0	11.0±1.0	8-9F
WTSQFDQ-Ia08	12.0±1.0	5.0±1.5	8.0±1.0	12.0±1.0	8-9F

First Issued: **2016-11-24**

Date: **2020-06-03**

Expiry Date: **2021-11-23**

...making excellence a habit.™

Page 11 of 33

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

# EC Design-Examination Certificate

## Supplementary Information to CE 650110

Issued To:

**Shanghai Shape Memory Alloy  
Co., Ltd.  
1F and 5F, Tower 41  
No. 258 XinZhuan Road  
Songjiang High-Tech Park  
CaoHeJing Development District  
Shanghai  
201612  
China**

**Device name: MemoPart™ VSD Occluder**

**Intended purpose per IFU:** The MemoPart™ Membranous VSD Occluder is used for minimally invasive transcatheter closure of perimembranous ventricular septal defects.

The MemoPart™ Muscular VSD Occluder is indicated for use in patients with a complex ventricular septal defect (VSD) of significant size to warrant closure (large volume left-to-right shunt, pulmonary hypertension, and/or clinical symptoms of congestive heart failure) who are considered to be at high risk for standard transatrial or transarterial surgical closure based on anatomical conditions and/or based on overall medical condition.

**Classification:** Class III Implant

Catalogue No	Model, type				
	LV Disc OD (mm)	Connecting waist height (mm)	Connecting waist OD (mm)	RV Disc OD (mm)	Smallest recommended Sheath
WTSQFDQ-Ia09	13.0±1.0	5.0±1.8	9.0±1.0	13.0±1.0	8-9F
WTSQFDQ-Ia10	14.0±1.0	5.0±1.8	10.0±1.2	14.0±1.0	9-10F
WTSQFDQ-Ia12	16.0±1.0	5.0±1.8	12.0±1.2	16.0±1.0	9-10F
WTSQFDQ-Ia14	18.0±1.0	5.0±1.8	14.0±1.5	18.0±1.0	10-12F
WTSQFDQ-Ia16	20.0±1.0	5.0±1.8	16.0±1.5	20.0±1.0	10-12F
WTSQFDQ-Ia18	22.0±1.0	5.0±1.8	18.0±1.5	22.0±1.0	10-12F
WTSQFDQ-Ib04	10.0±1.0	7.0±1.5	4.0±1.0	8.0±1.0	7-8F
WTSQFDQ-Ib05	11.0±1.0	7.0±1.5	5.0±1.0	9.0±1.0	7-8F
WTSQFDQ-Ib06	12.0±1.0	7.0±1.5	6.0±1.0	10.0±1.0	8-9F
WTSQFDQ-Ib07	13.0±1.0	7.0±1.5	7.0±1.0	11.0±1.0	8-9F
WTSQFDQ-Ib08	14.0±1.0	7.0±1.5	8.0±1.0	12.0±1.0	8-9F
WTSQFDQ-Ib09	15.0±1.0	7.0±1.8	9.0±1.0	13.0±1.0	8-9F
WTSQFDQ-Ib10	16.0±1.0	7.0±1.8	10.0±1.2	14.0±1.0	9-10F
WTSQFDQ-Ib12	18.0±1.0	7.0±1.8	12.0±1.2	16.0±1.0	9-10F
WTSQFDQ-Ib14	20.0±1.0	7.0±1.8	14.0±1.5	18.0±1.0	10-12F

First Issued: **2016-11-24**

Date: **2020-06-03**

Expiry Date: **2021-11-23**

...making excellence a habit.™

Page 12 of 33

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

# EC Design-Examination Certificate

## Supplementary Information to CE 650110

Issued To:

**Shanghai Shape Memory Alloy  
Co., Ltd.  
1F and 5F, Tower 41  
No. 258 XinZhuan Road  
Songjiang High-Tech Park  
CaoHeJing Development District  
Shanghai  
201612  
China**

**Device name: MemoPart™ VSD Occluder**

**Intended purpose per IFU:** The MemoPart™ Membranous VSD Occluder is used for minimally invasive transcatheter closure of perimembranous ventricular septal defects.

The MemoPart™ Muscular VSD Occluder is indicated for use in patients with a complex ventricular septal defect (VSD) of significant size to warrant closure (large volume left-to-right shunt, pulmonary hypertension, and/or clinical symptoms of congestive heart failure) who are considered to be at high risk for standard transatrial or transarterial surgical closure based on anatomical conditions and/or based on overall medical condition.

**Classification:** Class III Implant

Catalogue No	Model, type				
	LV Disc OD (mm)	Connecting waist height (mm)	Connecting waist OD (mm)	RV Disc OD (mm)	Smallest recommended Sheath
WTSQFDQ-Ib16	22.0±1.0	7.0±1.8	16.0±1.5	20.0±1.0	10-12F
WTSQFDQ-Ib18	24.0±1.0	7.0±1.8	18.0±1.5	22.0±1.0	10-12F
WTSQFDQ-Ic04	14.0±1.0	10.0±1.5	4.0±1.0	10.0±1.0	7-8F
WTSQFDQ-Ic05	15.0±1.0	10.0±1.5	5.0±1.0	11.0±1.0	7-8F
WTSQFDQ-Ic06	16.0±1.0	10.0±1.5	6.0±1.0	12.0±1.0	8-9F
WTSQFDQ-Ic07	17.0±1.0	10.0±1.5	7.0±1.0	13.0±1.0	8-9F
WTSQFDQ-Ic08	18.0±1.0	10.0±1.5	8.0±1.0	14.0±1.0	8-9F

First Issued: **2016-11-24**

Date: **2020-06-03**

Expiry Date: **2021-11-23**

...making excellence a habit.™

Page 13 of 33

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

# EC Design-Examination Certificate

## Supplementary Information to CE 650110

Issued To:

**Shanghai Shape Memory Alloy  
Co., Ltd.  
1F and 5F, Tower 41  
No. 258 XinZhuan Road  
Songjiang High-Tech Park  
CaoHeJing Development District  
Shanghai  
201612  
China**

<b>Device name: MemoPart™ VSD Occluder</b> <b>Intended purpose per IFU:</b> The MemoPart™ Membranous VSD Occluder is used for minimally invasive transcatheter closure of perimembranous ventricular septal defects. The MemoPart™ Muscular VSD Occluder is indicated for use in patients with a complex ventricular septal defect (VSD) of significant size to warrant closure (large volume left-to-right shunt, pulmonary hypertension, and/or clinical symptoms of congestive heart failure) who are considered to be at high risk for standard transatrial or transarterial surgical closure based on anatomical conditions and/or based on overall medical condition. <b>Classification:</b> Class III Implant					
Catalogue No	Model, type				
	LV Disc OD (mm)	Connecting waist height (mm)	Connecting waist OD (mm)	RV Disc OD (mm)	Smallest recommended Sheath
WTSQFDQ-Ic09	19.0±1.0	10.0±1.8	9.0±1.0	15.0±1.0	8-9F
WTSQFDQ-Ic10	20.0±1.0	10.0±1.8	10.0±1.2	16.0±1.0	9-10F
WTSQFDQ-Ic12	22.0±1.0	10.0±1.8	12.0±1.2	18.0±1.0	9-10F
WTSQFDQ-Ic14	24.0±1.0	10.0±1.8	14.0±1.5	20.0±1.0	10-12F
WTSQFDQ-Ic16	26.0±1.0	10.0±1.8	16.0±1.5	22.0±1.0	10-12F
WTSQFDQ-Ic18	28.0±1.0	10.0±1.8	18.0±1.5	24.0±1.0	10-12F
WTSQFDQ-Id04	18.0±1.0	10.0±1.5	4.0±1.0	10.0±1.0	7-8F
WTSQFDQ-Id05	19.0±1.0	10.0±1.5	5.0±1.0	11.0±1.0	7-8F
WTSQFDQ-Id06	20.0±1.0	10.0±1.5	6.0±1.0	12.0±1.0	8-9F
WTSQFDQ-Id07	21.0±1.0	10.0±1.5	7.0±1.0	13.0±1.0	8-9F
WTSQFDQ-Id08	22.0±1.0	10.0±1.5	8.0±1.0	14.0±1.0	8-9F
WTSQFDQ-Id09	23.0±1.0	10.0±1.8	9.0±1.0	15.0±1.0	8-9F
WTSQFDQ-Id10	24.0±1.0	10.0±1.8	10.0±1.2	16.0±1.0	9-10F
WTSQFDQ-Id12	26.0±1.0	10.0±1.8	12.0±1.2	18.0±1.0	9-10F

First Issued: **2016-11-24**

Date: **2020-06-03**

Expiry Date: **2021-11-23**

...making excellence a habit.™

Page 14 of 33

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.



# EC Design-Examination Certificate

## Supplementary Information to CE 650110

Issued To:

**Shanghai Shape Memory Alloy  
Co., Ltd.  
1F and 5F, Tower 41  
No. 258 XinZhuan Road  
Songjiang High-Tech Park  
CaoHeJing Development District  
Shanghai  
201612  
China**

**Device name: MemoPart™ VSD Occluder**

**Intended purpose per IFU:** The MemoPart™ Membranous VSD Occluder is used for minimally invasive transcatheter closure of perimembranous ventricular septal defects.

The MemoPart™ Muscular VSD Occluder is indicated for use in patients with a complex ventricular septal defect (VSD) of significant size to warrant closure (large volume left-to-right shunt, pulmonary hypertension, and/or clinical symptoms of congestive heart failure) who are considered to be at high risk for standard transatrial or transarterial surgical closure based on anatomical conditions and/or based on overall medical condition.

**Classification:** Class III Implant

Catalogue No	Model, type				
	LV Disc OD (mm)	Connecting waist height (mm)	Connecting waist OD (mm)	RV Disc OD (mm)	Smallest recommended Sheath
WTSQFDQ-Id14	28.0±1.0	10.0±1.8	14.0±1.5	20.0±1.0	10-12F
WTSQFDQ-Id16	30.0±1.0	10.0±1.8	16.0±1.5	22.0±1.0	10-12F
WTSQFDQ-Id18	32.0±1.0	10.0±1.8	18.0±1.5	24.0±1.0	10-12F
SQFDQ-IIa04	8.0±0.8	1.8±0.5	4.0±0.8	8.0±0.8	6-7F

First Issued: **2016-11-24**

Date: **2020-06-03**

Expiry Date: **2021-11-23**

...making excellence a habit.™

Page 15 of 33

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

# EC Design-Examination Certificate

## Supplementary Information to CE 650110

Issued To:

**Shanghai Shape Memory Alloy  
Co., Ltd.  
1F and 5F, Tower 41  
No. 258 XinZhuan Road  
Songjiang High-Tech Park  
CaoHeJing Development District  
Shanghai  
201612  
China**

**Device name: MemoPart™ VSD Occluder**

**Intended purpose per IFU:** The MemoPart™ Membranous VSD Occluder is used for minimally invasive transcatheter closure of perimembranous ventricular septal defects.

The MemoPart™ Muscular VSD Occluder is indicated for use in patients with a complex ventricular septal defect (VSD) of significant size to warrant closure (large volume left-to-right shunt, pulmonary hypertension, and/or clinical symptoms of congestive heart failure) who are considered to be at high risk for standard transatrial or transarterial surgical closure based on anatomical conditions and/or based on overall medical condition.

**Classification:** Class III Implant

Catalogue No	Model, type				
	LV Disc OD (mm)	Connecting waist height (mm)	Connecting waist OD (mm)	RV Disc OD (mm)	Smallest recommended Sheath
SQFDQ-IIa05	9.0±0.8	1.8±0.5	5.0±0.8	9.0±0.8	6-7F
SQFDQ-IIa06	10.0±0.8	1.8±0.5	6.0±0.8	10.0±0.8	7-8F
SQFDQ-IIa07	11.0±0.8	1.8±0.5	7.0±0.8	11.0±0.8	7-8F
SQFDQ-IIa08	12.0±0.8	1.8±0.5	8.0±0.8	12.0±0.8	7-8F
SQFDQ-IIa09	13.0±0.8	1.8±0.5	9.0±0.8	13.0±0.8	8-9F
SQFDQ-IIa10	14.0±0.8	1.8±0.5	10.0±0.8	14.0±0.8	8-9F
SQFDQ-IIa12	16.0±0.8	1.8±0.5	12.0±0.8	16.0±0.8	9-10F
SQFDQ-IIa14	18.0±0.8	1.8±0.5	14.0±0.8	18.0±0.8	9-10F
SQFDQ-IIa16	20.0±0.8	1.8±0.5	16.0±0.8	20.0±0.8	10-12F
SQFDQ-IIa18	24.0±0.8	1.8±0.5	18.0±0.8	22.0±0.8	10-12F
SQFDQ-IIa20	26.0±0.8	1.8±0.5	20.0±0.8	24.0±0.8	12-14F
SQFDQ-IIb04	8.0±0.8	3.5±1.0	4.0±0.8	8.0±0.8	6-7F
SQFDQ-IIb05	9.0±0.8	4.0±1.0	5.0±0.8	9.0±0.8	6-7F
SQFDQ-IIb06	10.0±0.8	4.0±1.0	6.0±1.0	10.0±0.8	7-8F

First Issued: **2016-11-24**

Date: **2020-06-03**

Expiry Date: **2021-11-23**

...making excellence a habit.™

Page 16 of 33

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

# EC Design-Examination Certificate

## Supplementary Information to CE 650110

Issued To:

**Shanghai Shape Memory Alloy  
Co., Ltd.  
1F and 5F, Tower 41  
No. 258 XinZhuan Road  
Songjiang High-Tech Park  
CaoHeJing Development District  
Shanghai  
201612  
China**

**Device name: MemoPart™ VSD Occluder**

**Intended purpose per IFU:** The MemoPart™ Membranous VSD Occluder is used for minimally invasive transcatheter closure of perimembranous ventricular septal defects.

The MemoPart™ Muscular VSD Occluder is indicated for use in patients with a complex ventricular septal defect (VSD) of significant size to warrant closure (large volume left-to-right shunt, pulmonary hypertension, and/or clinical symptoms of congestive heart failure) who are considered to be at high risk for standard transatrial or transarterial surgical closure based on anatomical conditions and/or based on overall medical condition.

**Classification:** Class III Implant

Catalogue No	Model, type				
	LV Disc OD (mm)	Connecting waist height (mm)	Connecting waist OD (mm)	RV Disc OD (mm)	Smallest recommended Sheath
SQFDQ-IIb07	11.0±1.0	4.0±1.0	7.0±1.0	11.0±1.0	7-8F
SQFDQ-IIb08	12.0±1.0	4.0±1.0	8.0±1.0	12.0±1.0	7-8F
SQFDQ-IIb09	13.0±1.0	4.5±1.0	9.0±1.2	13.0±1.0	8-9F
SQFDQ-IIb10	14.0±1.5	4.5±1.0	10.0±1.2	14.0±1.5	8-9F
SQFDQ-IIb12	16.0±1.5	4.5±1.0	12.0±1.5	15.0±1.5	9-10F
SQFDQ-IIb14	18.0±1.5	4.5±1.0	14.0±1.5	17.0±1.5	9-10F
SQFDQ-IIb16	22.0±1.5	5.0±1.0	16.0±1.5	20.0±1.5	10-12F
SQFDQ-IIb18	24.0±1.5	5.0±1.0	18.0±1.8	22.0±1.5	10-12F
SQFDQ-IIb20	26.0±1.5	5.0±1.0	20.0±1.8	24.0±1.5	12-14F
WTSQFDQ-IIa04	8.0±0.8	1.8±0.5	4.0±0.8	8.0±0.8	6-7F
WTSQFDQ-IIa05	9.0±0.8	1.8±0.5	5.0±0.8	9.0±0.8	6-7F
WTSQFDQ-IIa06	10.0±0.8	1.8±0.5	6.0±0.8	10.0±0.8	7-8F
WTSQFDQ-IIa07	11.0±0.8	1.8±0.5	7.0±0.8	11.0±0.8	7-8F
WTSQFDQ-IIa08	12.0±0.8	1.8±0.5	8.0±0.8	12.0±0.8	7-8F
WTSQFDQ-IIa09	13.0±0.8	1.8±0.5	9.0±0.8	13.0±0.8	8-9F

First Issued: **2016-11-24**

Date: **2020-06-03**

Expiry Date: **2021-11-23**

...making excellence a habit.™

Page 17 of 33

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

# EC Design-Examination Certificate

## Supplementary Information to CE 650110

Issued To:

**Shanghai Shape Memory Alloy  
Co., Ltd.  
1F and 5F, Tower 41  
No. 258 XinZhuan Road  
Songjiang High-Tech Park  
CaoHeJing Development District  
Shanghai  
201612  
China**

**Device name: MemoPart™ VSD Occluder**

**Intended purpose per IFU:** The MemoPart™ Membranous VSD Occluder is used for minimally invasive transcatheter closure of perimembranous ventricular septal defects.

The MemoPart™ Muscular VSD Occluder is indicated for use in patients with a complex ventricular septal defect (VSD) of significant size to warrant closure (large volume left-to-right shunt, pulmonary hypertension, and/or clinical symptoms of congestive heart failure) who are considered to be at high risk for standard transatrial or transarterial surgical closure based on anatomical conditions and/or based on overall medical condition.

**Classification:** Class III Implant

Catalogue No	Model, type				
	LV Disc OD (mm)	Connecting waist height (mm)	Connecting waist OD (mm)	RV Disc OD (mm)	Smallest recommended Sheath
WTSQFDQ-IIa10	14.0±0.8	1.8±0.5	10.0±0.8	14.0±0.8	8-9F
WTSQFDQ-IIa12	16.0±0.8	1.8±0.5	12.0±0.8	16.0±0.8	9-10F
WTSQFDQ-IIa14	18.0±0.8	1.8±0.5	14.0±0.8	18.0±0.8	9-10F
WTSQFDQ-IIa16	20.0±0.8	1.8±0.5	16.0±0.8	20.0±0.8	10-12F
WTSQFDQ-IIa18	24.0±0.8	1.8±0.5	18.0±0.8	22.0±0.8	10-12F
WTSQFDQ-IIa20	26.0±0.8	1.8±0.5	20.0±0.8	24.0±0.8	12-14F
WTSQFDQ-IIb04	8.0±0.8	3.5±1.0	4.0±0.8	8.0±0.8	6-7F
WTSQFDQ-IIb05	9.0±0.8	4.0±1.0	5.0±0.8	9.0±0.8	6-7F
WTSQFDQ-IIb06	10.0±0.8	4.0±1.0	6.0±1.0	10.0±0.8	7-8F
WTSQFDQ-IIb07	11.0±1.0	4.0±1.0	7.0±1.0	11.0±1.0	7-8F
WTSQFDQ-IIb08	12.0±1.0	4.0±1.0	8.0±1.0	12.0±1.0	7-8F
WTSQFDQ-IIb09	13.0±1.0	4.5±1.0	9.0±1.2	13.0±1.0	8-9F
WTSQFDQ-IIb10	14.0±1.5	4.5±1.0	10.0±1.2	14.0±1.5	8-9F
WTSQFDQ-IIb12	16.0±1.5	4.5±1.0	12.0±1.5	15.0±1.5	9-10F
WTSQFDQ-IIb14	18.0±1.5	4.5±1.0	14.0±1.5	17.0±1.5	9-10F

First Issued: **2016-11-24**

Date: **2020-06-03**

Expiry Date: **2021-11-23**

...making excellence a habit.™

Page 18 of 33

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

# EC Design-Examination Certificate

## Supplementary Information to CE 650110

Issued To:

**Shanghai Shape Memory Alloy  
Co., Ltd.  
1F and 5F, Tower 41  
No. 258 XinZhuan Road  
Songjiang High-Tech Park  
CaoHeJing Development District  
Shanghai  
201612  
China**

**Device name: MemoPart™ VSD Occluder**

**Intended purpose per IFU:** The MemoPart™ Membranous VSD Occluder is used for minimally invasive transcatheter closure of perimembranous ventricular septal defects.

The MemoPart™ Muscular VSD Occluder is indicated for use in patients with a complex ventricular septal defect (VSD) of significant size to warrant closure (large volume left-to-right shunt, pulmonary hypertension, and/or clinical symptoms of congestive heart failure) who are considered to be at high risk for standard transatrial or transarterial surgical closure based on anatomical conditions and/or based on overall medical condition.

**Classification:** Class III Implant

Catalogue No	Model, type				
	LV Disc OD (mm)	Connecting waist height (mm)	Connecting waist OD (mm)	RV Disc OD (mm)	Smallest recommended Sheath
WTSQFDQ-IIb16	22.0±1.5	5.0±1.0	16.0±1.5	20.0±1.5	10-12F
WTSQFDQ-IIb18	24.0±1.5	5.0±1.0	18.0±1.8	22.0±1.5	10-12F
WTSQFDQ-IIb20	26.0±1.5	5.0±1.0	20.0±1.8	24.0±1.5	12-14F
SQFDQ-III04	12.0±1.0	3.5±1.5	4.0±0.8	8.0±1.0	7-8F
SQFDQ-III05	13.0±1.0	4.0±1.5	5.0±1.0	9.0±1.0	8-9F
SQFDQ-III06	14.0±1.0	4.0±1.5	6.0±1.0	10.0±1.0	8-9F
SQFDQ-III07	15.0±1.0	4.0±1.5	7.0±1.2	11.0±1.0	8-9F
SQFDQ-III08	16.0±1.2	4.0±1.5	8.0±1.2	12.0±1.2	9-10F
SQFDQ-III09	17.0±1.2	4.5±1.5	9.0±1.2	13.0±1.2	9-10F
SQFDQ-III10	18.0±1.2	4.5±1.5	10.0±1.5	14.0±1.2	9-10F
SQFDQ-III12	20.0±1.5	4.5±1.5	12.0±1.5	16.0±1.2	10-12F
SQFDQ-III14	22.0±1.5	4.5±1.5	14.0±1.8	18.0±1.5	10-12F
SQFDQ-III16	24.0±1.5	5.0±1.5	16.0±1.8	20.0±1.5	10-12F

First Issued: **2016-11-24**

Date: **2020-06-03**

Expiry Date: **2021-11-23**

...making excellence a habit.™

Page 19 of 33

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.



# EC Design-Examination Certificate

## Supplementary Information to CE 650110

Issued To:

**Shanghai Shape Memory Alloy  
Co., Ltd.  
1F and 5F, Tower 41  
No. 258 XinZhuan Road  
Songjiang High-Tech Park  
CaoHeJing Development District  
Shanghai  
201612  
China**

**Device name: MemoPart™ VSD Occluder**

**Intended purpose per IFU:** The MemoPart™ Membranous VSD Occluder is used for minimally invasive transcatheter closure of perimembranous ventricular septal defects.

The MemoPart™ Muscular VSD Occluder is indicated for use in patients with a complex ventricular septal defect (VSD) of significant size to warrant closure (large volume left-to-right shunt, pulmonary hypertension, and/or clinical symptoms of congestive heart failure) who are considered to be at high risk for standard transatrial or transarterial surgical closure based on anatomical conditions and/or based on overall medical condition.

**Classification:** Class III Implant

Catalogue No	Model, type				
	LV Disc OD (mm)	Connecting waist height (mm)	Connecting waist OD (mm)	RV Disc OD (mm)	Smallest recommended Sheath
SQFDQ-III18	26.0±1.5	5.0±1.5	18.0±1.8	22.0±1.5	12-14F
WTSQFDQ-III04	12.0±1.0	3.5±1.5	4.0±0.8	8.0±1.0	7-8F
WTSQFDQ-III05	13.0±1.0	4.0±1.5	5.0±1.0	9.0±1.0	8-9F
WTSQFDQ-III06	14.0±1.0	4.0±1.5	6.0±1.0	10.0±1.0	8-9F
WTSQFDQ-III07	15.0±1.0	4.0±1.5	7.0±1.2	11.0±1.0	8-9F
WTSQFDQ-III08	16.0±1.2	4.0±1.5	8.0±1.2	12.0±1.2	9-10F
WTSQFDQ-III09	17.0±1.2	4.5±1.5	9.0±1.2	13.0±1.2	9-10F
WTSQFDQ-III10	18.0±1.2	4.5±1.5	10.0±1.5	14.0±1.2	9-10F
WTSQFDQ-III12	20.0±1.5	4.5±1.5	12.0±1.5	16.0±1.2	10-12F
WTSQFDQ-III14	22.0±1.5	4.5±1.5	14.0±1.8	18.0±1.5	10-12F
WTSQFDQ-III16	24.0±1.5	5.0±1.5	16.0±1.8	20.0±1.5	10-12F
WTSQFDQ-III18	26.0±1.5	5.0±1.5	18.0±1.8	22.0±1.5	12-14F
SQFDQ-IV04	9.0±2.0	3.5±1.5	4.0±0.8	8.0±1.0	7-8F
SQFDQ-IV05	10.0±2.0	3.5±1.5	5.0±0.8	9.0±1.0	7-8F

First Issued: **2016-11-24**

Date: **2020-06-03**

Expiry Date: **2021-11-23**

...making excellence a habit.™

Page 20 of 33

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

# EC Design-Examination Certificate

## Supplementary Information to CE 650110

Issued To:

**Shanghai Shape Memory Alloy  
Co., Ltd.  
1F and 5F, Tower 41  
No. 258 XinZhuan Road  
Songjiang High-Tech Park  
CaoHeJing Development District  
Shanghai  
201612  
China**

**Device name: MemoPart™ VSD Occluder**

**Intended purpose per IFU:** The MemoPart™ Membranous VSD Occluder is used for minimally invasive transcatheter closure of perimembranous ventricular septal defects.

The MemoPart™ Muscular VSD Occluder is indicated for use in patients with a complex ventricular septal defect (VSD) of significant size to warrant closure (large volume left-to-right shunt, pulmonary hypertension, and/or clinical symptoms of congestive heart failure) who are considered to be at high risk for standard transatrial or transarterial surgical closure based on anatomical conditions and/or based on overall medical condition.

**Classification:** Class III Implant

Catalogue No	Model, type				
	LV Disc OD (mm)	Connecting waist height (mm)	Connecting waist OD (mm)	RV Disc OD (mm)	Smallest recommended Sheath
SQFDQ-IV06	11.0±2.0	4.0±1.5	6.0±1.0	10.0±1.0	7-8F
SQFDQ-IV07	12.0±2.5	4.0±1.5	7.0±1.0	11.0±1.0	8-9F
SQFDQ-IV08	13.0±2.5	4.5±1.5	8.0±1.2	12.0±1.2	8-9F
SQFDQ-IV09	14.0±2.5	5.0±1.5	9.0±1.2	13.0±1.2	9-10F

First Issued: **2016-11-24**

Date: **2020-06-03**

Expiry Date: **2021-11-23**

...making excellence a habit.™

Page 21 of 33

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

# EC Design-Examination Certificate

## Supplementary Information to CE 650110

Issued To:

**Shanghai Shape Memory Alloy  
Co., Ltd.  
1F and 5F, Tower 41  
No. 258 XinZhuan Road  
Songjiang High-Tech Park  
CaoHeJing Development District  
Shanghai  
201612  
China**

**Device name: MemoPart™ VSD Occluder**

**Intended purpose per IFU:** The MemoPart™ Membranous VSD Occluder is used for minimally invasive transcatheter closure of perimembranous ventricular septal defects.

The MemoPart™ Muscular VSD Occluder is indicated for use in patients with a complex ventricular septal defect (VSD) of significant size to warrant closure (large volume left-to-right shunt, pulmonary hypertension, and/or clinical symptoms of congestive heart failure) who are considered to be at high risk for standard transatrial or transarterial surgical closure based on anatomical conditions and/or based on overall medical condition.

**Classification:** Class III Implant

Catalogue No	Model, type				
	LV Disc OD (mm)	Connecting waist height (mm)	Connecting waist OD (mm)	RV Disc OD (mm)	Smallest recommended Sheath
SQFDQ-IV10	17.0±2.5	5.0±1.5	10.0±1.7	15.0±1.2	9-10F
SQFDQ-IV12	20.0±3.5	5.0±1.5	12.0±1.7	18.0±1.2	10-12F
SQFDQ-IV14	22.0±3.5	5.0±1.5	14.0±1.8	20.0±1.5	10-12F
SQFDQ-IV16	24.0±3.5	5.0±1.5	16.0±1.8	22.0±1.5	10-12F
WTSQFDQ-IV04	9.0±2.0	3.5±1.5	4.0±0.8	8.0±1.0	7-8F
WTSQFDQ-IV05	10.0±2.0	3.5±1.5	5.0±0.8	9.0±1.0	7-8F
WTSQFDQ-IV06	11.0±2.0	4.0±1.5	6.0±1.0	10.0±1.0	7-8F
WTSQFDQ-IV07	12.0±2.5	4.0±1.5	7.0±1.0	11.0±1.0	8-9F
WTSQFDQ-IV08	13.0±2.5	4.5±1.5	8.0±1.2	12.0±1.2	8-9F
WTSQFDQ-IV09	14.0±2.5	5.0±1.5	9.0±1.2	13.0±1.2	9-10F
WTSQFDQ-IV10	17.0±2.5	5.0±1.5	10.0±1.7	15.0±1.2	9-10F
WTSQFDQ-IV12	20.0±3.5	5.0±1.5	12.0±1.7	18.0±1.2	10-12F
WTSQFDQ-IV14	22.0±3.5	5.0±1.5	14.0±1.8	20.0±1.5	10-12F
WTSQFDQ-IV16	24.0±3.5	5.0±1.5	16.0±1.8	22.0±1.5	10-12F

First Issued: **2016-11-24**

Date: **2020-06-03**

Expiry Date: **2021-11-23**

...making excellence a habit.™

Page 22 of 33

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

# EC Design-Examination Certificate

## Supplementary Information to CE 650110

Issued To:

**Shanghai Shape Memory Alloy  
Co., Ltd.  
1F and 5F, Tower 41  
No. 258 XinZhuan Road  
Songjiang High-Tech Park  
CaoHeJing Development District  
Shanghai  
201612  
China**

<b>Device name: MemoPart™ PDA Occluder</b> <b>Intended purpose per IFU:</b> The MemoPart™ PDA Occluder can be used for the nonsurgical closure of apatent ductus arteriosus (PDA) in the percutaneous, transcatheter therapy. <b>Classification:</b> Class III Implant					
Catalogue No	Model, type				
	Aortic disc OD (mm)	Connecting waist height (mm)	Aortic waist OD (mm)	Pulmonic waist OD (mm)	Smallest recommended Sheath
WBFDQ-I04	8.0±1.0	4.0±1.5	4.0±1.0	--	6-7F
WBFDQ-I05	9.0±1.0	5.0±1.5	5.0±1.0	--	6-7F
WBFDQ-I06	10.0±1.0	6.0±1.5	6.0±1.0	--	6-7F
WBFDQ-I07	11.0±1.0	6.5±1.5	7.0±1.0	--	7-8F
WBFDQ-I08	12.0±1.0	6.5±1.5	8.0±1.0	--	7-8F
WBFDQ-I09	13.0±1.0	7.0±1.5	9.0±1.0	--	8-9F
WBFDQ-I10	14.0±1.5	7.5±2.0	10.0±1.5	--	8-9F
WBFDQ-I11	15.0±1.5	8.0±2.0	11.0±1.5	--	8-9F
WBFDQ-I12	16.0±1.5	8.5±2.0	12.0±1.5	--	8-9F
WBFDQ-I13	17.0±1.5	8.5±2.0	13.0±1.5	--	8-9F
WBFDQ-I14	18.0±1.5	9.5±2.0	14.0±1.5	--	9-10F
WBFDQ-I16	21.0±2.0	10.5±2.5	16.0±2.0	--	9-10F
WBFDQ-I18	23.0±2.0	10.5±2.5	18.0±2.0	--	10-12F
WBFDQ-I20	25.0±2.0	12±2.5	20.0±2.0	--	12-14F
WBFDQ-I22	27.0±2.0	12±2.5	22.0±2.0	--	12-14F
WBFDQ-II06	10.0±1.0	6.0±1.5	6.0±1.0	4.0±1.0	6-7F

First Issued: **2016-11-24**

Date: **2020-06-03**

Expiry Date: **2021-11-23**

...making excellence a habit.™

Page 23 of 33

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

# EC Design-Examination Certificate

## Supplementary Information to CE 650110

Issued To:

**Shanghai Shape Memory Alloy  
Co., Ltd.  
1F and 5F, Tower 41  
No. 258 XinZhuan Road  
Songjiang High-Tech Park  
CaoHeJing Development District  
Shanghai  
201612  
China**

<b>Device name: MemoPart™ PDA Occluder</b> <b>Intended purpose per IFU:</b> The MemoPart™ PDA Occluder can be used for the nonsurgical closure of apatent ductus arteriosus (PDA) in the percutaneous, transcatheter therapy. <b>Classification:</b> Class III Implant					
Catalogue No	Model, type				
	Aortic disc OD (mm)	Connecting waist height (mm)	Aortic waist OD (mm)	Pulmonic waist OD (mm)	Smallest recommended Sheath
WBFDQ-II08	12.0±1.0	6.5±1.5	8.0±1.0	6.0±1.0	7-8F
WBFDQ-II10	14.0±1.5	7.5±2.0	10.0±1.5	8.0±1.5	7-8F
WBFDQ-II12	16.0±1.5	8.5±2.0	12.0±1.5	10.0±1.5	8-9F
WBFDQ-II14	18.0±1.5	9.5±2.0	14.0±1.5	12.0±1.5	8-9F
WBFDQ-II16	20.0±1.5	10.5±2.5	16.0±2.0	14.0±2.0	9-10F
WBFDQ-II18	23.0±2.0	10.5±2.5	18.0±2.0	16.0±2.0	10-12F
WBFDQ-II20	25.0±2.0	12.0±2.5	20.0±2.0	18.0±2.0	12-14F
WBFDQ-II22	27.0±2.0	12.0±2.5	22.0±2.0	20.0±2.0	12-14F
WTWBFDQ-I04	8.0±1.0	4.0±1.5	4.0±1.0	--	6-7F
WTWBFDQ-I05	9.0±1.0	5.0±1.5	5.0±1.0	--	6-7F
WTWBFDQ-I06	10.0±1.0	6.0±1.5	6.0±1.0	--	6-7F
WTWBFDQ-I07	11.0±1.0	6.5±1.5	7.0±1.0	--	7-8F
WTWBFDQ-I08	12.0±1.0	6.5±1.5	8.0±1.0	--	7-8F
WTWBFDQ-I09	13.0±1.0	7.0±1.5	9.0±1.0	--	8-9F
WTWBFDQ-I10	14.0±1.5	7.5±2.0	10.0±1.5	--	8-9F
WTWBFDQ-I11	15.0±1.5	8.0±2.0	11.0±1.5	--	8-9F
WTWBFDQ-I12	16.0±1.5	8.5±2.0	12.0±1.5	--	8-9F

First Issued: **2016-11-24**

Date: **2020-06-03**

Expiry Date: **2021-11-23**

...making excellence a habit.™

Page 24 of 33

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.



# EC Design-Examination Certificate

## Supplementary Information to CE 650110

Issued To:

**Shanghai Shape Memory Alloy  
Co., Ltd.  
1F and 5F, Tower 41  
No. 258 XinZhuan Road  
Songjiang High-Tech Park  
CaoHeJing Development District  
Shanghai  
201612  
China**

<b>Device name: MemoPart™ PDA Occluder</b> <b>Intended purpose per IFU:</b> The MemoPart™ PDA Occluder can be used for the nonsurgical closure of a patent ductus arteriosus (PDA) in the percutaneous, transcatheter therapy. <b>Classification:</b> Class III Implant					
Catalogue No	Model, type				
	Aortic disc OD (mm)	Connecting waist height (mm)	Aortic waist OD (mm)	Pulmonic waist OD (mm)	Smallest recommended Sheath
WTWBFDQ-II13	17.0±1.5	8.5±2.0	13.0±1.5	--	8-9F
WTWBFDQ-II14	18.0±1.5	9.5±2.0	14.0±1.5	--	9-10F
WTWBFDQ-II16	21.0±2.0	10.5±2.5	16.0±2.0	--	9-10F
WTWBFDQ-II18	23.0±2.0	10.5±2.5	18.0±2.0	--	10-12F
WTWBFDQ-II20	25.0±2.0	12±2.5	20.0±2.0	--	12-14F
WTWBFDQ-II22	27.0±2.0	12±2.5	22.0±2.0	--	12-14F
WTWBFDQ-II06	9.0±1.0	6.0±1.5	6.0±1.0	4.0±1.0	6-7F
WTWBFDQ-II08	11.0±1.0	6.5±1.5	8.0±1.0	6.0±1.0	7-8F
WTWBFDQ-II10	14.0±1.5	7.5±2.0	10.0±1.5	8.0±1.5	7-8F
WTWBFDQ-II12	16.0±1.5	8.5±2.0	12.0±1.5	10.0±1.5	8-9F
WTWBFDQ-II14	18.0±1.5	9.5±2.0	14.0±1.5	12.0±1.5	8-9F
WTWBFDQ-II16	20.0±1.5	10.5±2.5	16.0±2.0	14.0±2.0	9-10F
WTWBFDQ-II18	23.0±2.0	10.5±2.5	18.0±2.0	16.0±2.0	10-12F
WTWBFDQ-II20	25.0±2.0	12.0±2.5	20.0±2.0	18.0±2.0	12-14F
WTWBFDQ-II22	27.0±2.0	12.0±2.5	22.0±2.0	20.0±2.0	12-14F

First Issued: **2016-11-24**

Date: **2020-06-03**

Expiry Date: **2021-11-23**

...making excellence a habit.™

Page 25 of 33

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

# EC Design-Examination Certificate

## Supplementary Information to CE 650110

Issued To:

**Shanghai Shape Memory Alloy  
Co., Ltd.  
1F and 5F, Tower 41  
No. 258 XinZhuan Road  
Songjiang High-Tech Park  
CaoHeJing Development District  
Shanghai  
201612  
China**

**Device name: MemoPart™ PFO Occluder**

**Intended purpose per IFU:** The MemoPart™ PFO Occluder is a percutaneous, transcatheter occlusion device intended to close all types PFOs (i.e. classical as well as those with aneurysm of the septum) in patients with a history of stroke or transient ischemic attacks (TIAs) diagnosed by echocardiography with right-to-left shunting during the Valsalva maneuver.

**Classifications:** Class III Implant

Catalogue No	Model, type				
	Connecting waist OD (mm)	Connecting waist height (mm)	LA Disc OD (mm)	RA Disc OD (mm)	Smallest recommended Sheath
LYKFDQ-I1818	3.5±1.0	6.0±2.0	18.0±2.0	18.0±2.0	10-12F
LYKFDQ-I1824	4.0±1.0	7.0±2.0	18.0±2.0	24.0±2.0	10-12F
LYKFDQ-I2424	4.0±1.0	7.0±2.0	24.0±2.0	24.0±2.0	10-12F
LYKFDQ-I2228	4.5±1.0	7.0±2.0	22.0±2.0	28.0±2.0	12-14F
LYKFDQ-I2828	4.5±1.0	7.0±2.0	28.0±2.0	28.0±2.0	12-14F
LYKFDQ-I2534	5.0±1.0	7.0±2.0	25.0±2.0	34.0±2.0	12-14F
LYKFDQ-I3434	5.0±1.0	7.0±2.0	34.0±2.0	34.0±2.0	12-14F
WTLYKFDQ-I1818	3.5±1.0	6.0±2.0	18.0±2.0	18.0±2.0	10-12F
WTLYKFDQ-I1824	4.0±1.0	7.0±2.0	18.0±2.0	24.0±2.0	10-12F
WTLYKFDQ-I2424	4.0±1.0	7.0±2.0	24.0±2.0	24.0±2.0	10-12F
WTLYKFDQ-I2228	4.5±1.0	7.0±2.0	22.0±2.0	28.0±2.0	12-14F
WTLYKFDQ-I2828	4.5±1.0	7.0±2.0	28.0±2.0	28.0±2.0	12-14F
WTLYKFDQ-I2534	5.0±1.0	7.0±2.0	25.0±2.0	34.0±2.0	12-14F
WTLYKFDQ-I3434	5.0±1.0	7.0±2.0	34.0±2.0	34.0±2.0	12-14F

First Issued: **2016-11-24**

Date: **2020-06-03**

Expiry Date: **2021-11-23**

...making excellence a habit.™

Page 26 of 33

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

# EC Design-Examination Certificate

## Supplementary Information to CE 650110

Issued To:

**Shanghai Shape Memory Alloy  
Co., Ltd.  
1F and 5F, Tower 41  
No. 258 XinZhuan Road  
Songjiang High-Tech Park  
CaoHeJing Development District  
Shanghai  
201612  
China**

### Device name: MemoPart™ Plug

**Intended purpose per IFU:** The MemoPart™ Vascular Plug can be used for a wide variety of occlusions of veins or arteries. Reducing or eliminating blood flow to an area of the body by blocking. Plug can be used for patients with clinical symptoms of abnormal blood vessels, such as:

- Aortopulmonary collaterals
- Arteriovenous malformation
- Surgical aortopulmonary shunts
- Anomalous venovenous connections
- Arteriovenous fistulas
- Peripheral vessels

**Classification:** Class III Implant

Catalogue No	Model, type		
	Waist height (mm)	Waist Length (mm)	Smallest recommended Sheath
XGSFDQ-I04	5.0±0.5	4.0±0.5	6-7F
XGSFDQ-I06	6.5±0.5	6.0±0.5	7-8F
XGSFDQ-I08	7.5±0.5	8.0±0.5	7-8F
XGSFDQ-I10	8.5±0.75	10.0±0.5	8-9F
XGSFDQ-I12	9.5±0.75	12.0±0.75	8-9F
XGSFDQ-I14	10.5±0.75	14.0±0.75	9-10F
XGSFDQ-I16	11.0±1.0	16.0±0.75	9-10F
XGSFDQ-I18	11.0±1.0	18.0±0.75	10-12F
XGSFDQ-I20	12.0±1.0	20.0±1.0	10-12F
XGSFDQ-I22	13.0±1.0	22.0±1.0	10-12F

First Issued: **2016-11-24**

Date: **2020-06-03**

Expiry Date: **2021-11-23**

...making excellence a habit.™

Page 27 of 33

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

# EC Design-Examination Certificate

## Supplementary Information to CE 650110

Issued To:

**Shanghai Shape Memory Alloy  
Co., Ltd.  
1F and 5F, Tower 41  
No. 258 XinZhuan Road  
Songjiang High-Tech Park  
CaoHeJing Development District  
Shanghai  
201612  
China**

**Device name: MemoPart™ Plug**

**Intended purpose per IFU:** The MemoPart™ Vascular Plug can be used for a wide variety of occlusions of veins or arteries. Reducing or eliminating blood flow to an area of the body by blocking. Plug can be used for patients with clinical symptoms of abnormal blood vessels, such as:

- Aortopulmonary collaterals
- Arteriovenous malformation
- Surgical aortopulmonary shunts
- Anomalous venovenous connections
- Arteriovenous fistulas
- Peripheral vessels

**Classification:** Class III Implant

Catalogue No	Model, type		
	Waist height (mm)	Waist Length (mm)	Smallest recommended Sheath
WTXGSFDQ-I04	5.0±0.5	4.0±0.5	6-7F
WTXGSFDQ-I06	6.5±0.5	6.0±0.5	7-8F
WTXGSFDQ-I08	7.5±0.5	8.0±0.5	7-8F
WTXGSFDQ-I10	8.5±0.75	10.0±0.5	8-9F
WTXGSFDQ-I12	9.5±0.75	12.0±0.75	8-9F
WTXGSFDQ-I14	10.5±0.75	14.0±0.75	9-10F
WTXGSFDQ-I16	11.0±1.0	16.0±0.75	9-10F
WTXGSFDQ-I18	11.0±1.0	18.0±0.75	10-12F
WTXGSFDQ-I20	12.0±1.0	20.0±1.0	10-12F
WTXGSFDQ-I22	13.0±1.0	22.0±1.0	10-12F

First Issued: **2016-11-24**

Date: **2020-06-03**

Expiry Date: **2021-11-23**

...making excellence a habit.™

Page 28 of 33

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

# EC Design-Examination Certificate

## Supplementary Information to CE 650110

Issued To:

**Shanghai Shape Memory Alloy  
Co., Ltd.  
1F and 5F, Tower 41  
No. 258 XinZhuan Road  
Songjiang High-Tech Park  
CaoHeJing Development District  
Shanghai  
201612  
China**

**Device name: MemoPart™ Occluder Delivery System**

**Intended purpose per IFU:** MemoPart™ Occluder Delivery System is intended to provide a pathway through which devices are introduced within the chambers and coronary vasculature of the heart or in the peripheral vasculature.

**Classification:** Class III

Catalogue No	Model, type								
	Loader		Long sheath			Dilator	Pusher		
	ID (mm, ±0.25)	Effective Length (mm, ±30)	ID (mm, ±0.25)	Effective Length (mm, ±60)	Angle (±20°)	Effective Length (mm, ±60)	Effective Length (mm, ±50)	OD (mm, ±0.20)	Screw OD (mm, ±0.06)
ODS-A-I-5F	(mm, ±30)	130	1.85	800	45°	920	1200	1.4	0.80
ODS-A-I-6F	1.85	130	2.00	800	45°	920	1200	1.6	0.80
ODS-A-I-7F	2.00	130	2.33	800	45°	920	1200	1.8	0.80
ODS-A-I-8F	2.33	130	2.67	800	45°	920	1200	1.8	0.80
ODS-A-I-9F	2.67	130	3.00	800	45°	920	1200	1.8	0.80
ODS-A-I-10F	3.00	130	3.33	800	45°	920	1200	1.9	0.80
ODS-A-I-12F	3.33	160	4.00	800	45°	920	1200	2.0	0.80
ODS-A-I-14F	4.00	160	4.67	800	45°	920	1200	2.0	0.80
ODS-P/V-II-5F	4.67	130	1.85	800	180°	920	1200	1.4	0.80
ODS-P/V-II-6F	1.85	130	2.00	800	180°	920	1200	1.6	0.80
ODS-P/V-II-7F	2.00	130	2.33	800	180°	920	1200	1.8	0.80
ODS-P/V-II-8F	2.33	130	2.67	800	180°	920	1200	1.8	0.80
ODS-P/V-II-9F	2.67	130	3.00	800	180°	920	1200	1.8	0.80
ODS-P/V-II-10F	3.00	130	3.33	800	180°	920	1200	1.9	0.80
ODS-P/V-II-12F	3.33	160	4.00	800	180°	920	1200	2.0	0.80
ODS-P/V-II-14F	4.00	160	4.67	800	180°	920	1200	2.0	0.80
ODS-A-III-5F	4.67	130	1.85	600	45°	680	1200	1.4	0.80

First Issued: **2016-11-24**

Date: **2020-06-03**

Expiry Date: **2021-11-23**

...making excellence a habit.™

Page 29 of 33

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.



# EC Design-Examination Certificate

## Supplementary Information to CE 650110

Issued To:

**Shanghai Shape Memory Alloy  
Co., Ltd.  
1F and 5F, Tower 41  
No. 258 XinZhuan Road  
Songjiang High-Tech Park  
CaoHeJing Development District  
Shanghai  
201612  
China**

**Device name: MemoPart™ Occluder Delivery System**

**Intended purpose per IFU:** MemoPart™ Occluder Delivery System is intended to provide a pathway through which devices are introduced within the chambers and coronary vasculature of the heart or in the peripheral vasculature.

**Classification:** Class III

Catalogue No	Model, type								
	Loader		Long sheath			Dilator	Pusher		
	ID (mm, ±0.25)	Effective Length (mm, ±30)	ID (mm, ±0.25)	Effective Length (mm, ±60)	Angle (±20°)	Effective Length (mm, ±60)	Effective Length (mm, ±50)	OD (mm, ±0.20)	Screw OD (mm, ±0.06)
ODS-A-III-6F	2.00	130	2.00	600	45°	680	1200	1.6	0.80
ODS-A-III-7F	2.33	130	2.33	600	45°	680	1200	1.8	0.80
ODS-A-III-8F	2.67	130	2.67	600	45°	680	1200	1.8	0.80
ODS-A-III-9F	3.00	130	3.00	600	45°	680	1200	1.8	0.80
ODS-A-III-10F	3.33	130	3.33	600	45°	680	1200	1.9	0.80
ODS-A-III-12F	4.00	160	4.00	600	45°	680	1200	2.0	0.80
ODS-A-III-14F	4.67	160	4.67	600	45°	680	1200	2.0	0.80
ODS-P/V-IV-5F	1.85	130	1.85	600	180°	680	1200	1.4	0.80
ODS-P/V-IV-6F	2.00	130	2.00	600	180°	680	1200	1.6	0.80
ODS-P/V-IV-7F	2.33	130	2.33	600	180°	680	1200	1.8	0.80
ODS-P/V-IV-8F	2.67	130	2.67	600	180°	680	1200	1.8	0.80
ODS-P/V-IV-9F	3.00	130	3.00	600	180°	680	1200	1.8	0.80

First Issued: **2016-11-24**

Date: **2020-06-03**

Expiry Date: **2021-11-23**

...making excellence a habit.™

Page 30 of 33

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

# EC Design-Examination Certificate

## Supplementary Information to CE 650110

Issued To:

**Shanghai Shape Memory Alloy  
Co., Ltd.  
1F and 5F, Tower 41  
No. 258 XinZhuan Road  
Songjiang High-Tech Park  
CaoHeJing Development District  
Shanghai  
201612  
China**

**Device name: MemoPart™ Occluder Delivery System**

**Intended purpose per IFU:** MemoPart™ Occluder Delivery System is intended to provide a pathway through which devices are introduced within the chambers and coronary vasculature of the heart or in the peripheral vasculature.

**Classification:** Class III

Catalogue No	Model, type								
	Loader		Long sheath			Dilator	Pusher		
	ID (mm, ±0.25)	Effective Length (mm, ±30)	ID (mm, ±0.25)	Effective Length (mm, ±60)	Angle (±20°)	Effective Length (mm, ±60)	Effective Length (mm, ±50)	OD (mm, ±0.20)	Screw OD (mm, ±0.06)
ODS-P/V-IV-10F	3.33	130	3.33	600	180°	680	1200	1.9	0.80
ODS-P/V-IV-12F	4.00	160	4.00	600	180°	680	1200	2.0	0.80
ODS-P/V-IV-14F	4.67	160	4.67	600	180°	680	1200	2.0	0.80

First Issued: **2016-11-24**

Date: **2020-06-03**

Expiry Date: **2021-11-23**

...making excellence a habit.™

Page 31 of 33

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

# EC Design-Examination Certificate

## Supplementary Information to CE 650110

Issued To:

**Shanghai Shape Memory Alloy  
Co., Ltd.  
1F and 5F, Tower 41  
No. 258 XinZhuan Road  
Songjiang High-Tech Park  
CaoHeJing Development District  
Shanghai  
201612  
China**

**Device name: MemoPart™ Snare**

Intended purpose per IFU: The MemoPart™ Snare is used in the retrieval and manipulation of atraumatic foreign bodies located in the coronary and peripheral cardiovascular system.

**Classification:** Class III

Catalogue No	Model, type		
	Effective Length, mm	Circle diameter, mm	Angle
Snare-15	1240±60	15±2	90°±20°
Snare-20	1240±60	20±2	90°±20°

First Issued: **2016-11-24**

Date: **2020-06-03**

Expiry Date: **2021-11-23**

...making excellence a habit.™

Page 32 of 33

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

# EC Design-Examination Certificate

## Supplementary Information to CE 650110

Issued To:

**Shanghai Shape Memory Alloy  
Co., Ltd.  
1F and 5F, Tower 41  
No. 258 XinZhuan Road  
Songjiang High-Tech Park  
CaoHeJing Development District  
Shanghai  
201612  
China**

## Certificate History

Date	Reference Number	Action
24 November 2016	10161708	First issue.
01 March 2019	8250592	Traceable to NB 0086.
20 November 2019	9771438	Change affecting Tyvek 1073B® packaging materials – all product codes are affected.
Current	8953253	Change of sterilization parameters. Administrative change on product table.

First Issued: **2016-11-24**

Date: **2020-06-03**

Expiry Date: **2021-11-23**

...making excellence a habit.™

Page 33 of 33

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.