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Hemostasis Valve Sets

· Hemostasis valve set is intended to connect/introduce catheter/guide wire to facilitate the fulfillment of surgery. Hemostasis valve is designed to be used as a conduit when interventional devices are inserted into the human vascular system. Guide wire insertion tool is used to facilitate entry of the guide wire into the hemostasis valve. It consists of an austenitic stainless steel tube connected to a hub constructed of polycarbonate. Torque device is used to manipulate the steering of a guidewire within the vascular regions.

INQUIRY

FEATURES

- Pressure resistance and good sealing vale to reduce the blood loss
- Various types to meet the clinician's habits available in 4 types, of which 2 main types are unique in



- 2) Push pull type (press to turn off, and press to pop up).
- 3) Another main type: a special Y valve customized for neurosurgeons (unique in China), with a short appearance of 2-3cm, which is popular with neurosurgeons. In the past, the Y-valves used in the neurosurgery department were all from heart surgery and then modified by doctors. This customized type saves operating time and improves convenience.

CONTENTS

Hemostasis Valve
Guide Wire Insertion Tool
Torque Device





Hemostasis Valve Sets | Haemostasis Valve | SCW Medicath





PARAMETER

Product No.	Description
42.03.10000	Twist Y Connector
42.03.10001	Push Pull Y connector
42.03.10004	Y Click type
42.03.10005	Twist Y connector with 25cm extension line and stopcocks
42.03.10002	Push Pull Y connector with 25cm extension line and stopcocks
42.03.10006	Y Click type with 25cm extension line and stopcocks
42.03.10003	Push Pull Y connector with 45cm extension line and stopcocks
42.03.10012	Y Click type with 45cm extension line and stopcocks
42.03.10053	Hemostasis Valve Set (two valves)
42.03.10054	Push pull with Green



Manufacturer:

whose single Authorized Representative

SCW MEDICATH LTD.

OBELIS S.A.

NO.4, Baolong 6th Road, Baolong Industrial Town, Longgang District, Shenzhen, Bd. Général Wahis 53 1030 Brussels, Belgium

518116, Guangdong, P.R. China

We, the manufacturer, herewith declare that the products

Hemostasis Valve Sets

Models: SCW-HV, SCW-HV-1, SCW-HV-2, SCW-HV-3, SCW-HV-4, SCW-HV-5, SCW-HV-6

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class Is according to Annex IX Rule 2 of the Directive 93/42/EEC. It bears the mark

C € 0197

The product concerned has been manufactured under a quality management system according to Annex II of Directive 93/42/EEC.

Compliance of the designated product with the Directive 93/42/EEC has been assured via assessment of the quality management system by the Notified Body

TÜV Rheinland LGA Products GmbH Tillystraße 2 90431 Nürnberg Deutschland Certificate No.: HD 60144232 0001

Issue date: 26.05.2020 Expiry date: 26.05.2024

following the procedure relating to the EC Declaration of Conformity set out in Annex II of Directive 93/42/EEC.

For Class Is product only. Application of the abovementioned Annexes and the intervention by the Notified Body is limited to: the aspects of manufacture concerned with securing and maintaining sterile conditions.

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

The above mentioned declaration of conformity is exclusively under the responsibility of

SCW MEDICATH LTD.

NO.4, Baolong 6th Road, Baolong Industrial Town,
Longgang District, Shenzhen, 518116, Guangdong, P.R. China

Shenzhen, 2020/07/16

Place, date

Miriam XIE, RA

Legally binding signature, Function



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