	Document Name	Declaration of Conformity			Page	Page 1 of 1
	Document No.	CE-CV-01-01	Version	V01	Effective Date	2020-06-20

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European Representative: OBELIS S.A
 Bd Général Wahis, 53 B-1030 Brussels, Belgium
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Product Name Catheter Valve
Types: 03/02/10/00/GHC
UMDNs Code: 14325

Classification (MDD, Annex IX): Class Is / rule 1
Conformity Assessment Route: Annex V

We herewith declare in sole responsibility that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer. We are exclusively responsible for the declaration of conformity.

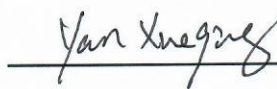
DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany
Identification number: 0123
(EC) Certificate(s): G2S 0052250004 REV.01
Expire date of the Certificate: 2023-12-03
Start of CE Marking: Not yet
Place of Issue: Hangzhou, PEOPLE'S REPUBLIC OF CHINA
Date of Issue: 2020-06-20

Signature:


 Yan Xueqing

Position: Management Representative