Declaration of Conformity

In accordance with Medical Device Directive 93/42/EEC.

Manufacturer	**European Authorized Representative**
Name: Zhejiang Zylox Medical Device Co., Ltd.	**Name:** Shanghai International Holding Corp. GmbH (Europe)
Address: Floor 1& 2, Building No.1, 18 Keji Avenue, Yuhang Street, Yuhang District, 311121, Hangzhou PEOPLE'S PEPUBLIC OF CHINA	**Address:** Eiffestrasse 80 20537 Hamburg Germany
SRN: CN-MF-000010626	**SRN:** DE-AR-000000001

We, herewith declare that the under mentioned device, in view of its design and type of construction, meets the essential health and safety requirements of the above EC Directive 93/42/EEC as amended by Directive 2007/47/EC. If the device is modified without the agreement of the under-designed, this declaration becomes invalid.

Device name	HP PTA Balloon Catheter
Brand name	ZENFlow™
Model name	Refer to Annex 1.
Risk Class and rules	Rule 6, IIa
Conformity Assessment route	Annex II, Council Directive 93/42/EEC (without II. 4)
GMDN code	17184
Basic UDI-DI	697197181Balloon13Q5
Notified body	TÜV SÜD Product Service GmbH
EC Certificate No.	G10905300004 Rev.02
Initial issue date of EC Certificate	October 10, 2018
Expiry date of EC certificate	May 26, 2024

The product identified above complies with the essential requirements of the above EC Directives by meeting the standards listed in Annex 2.

Name of authorized signatory: Tao Li

Signature with date: Tao Li 30.6.2023

Position: Person responsible for regulatory compliance

Place: Hangzhou, Zhejiang, China

Digitally signed by Ostapciuc Alexandr
Date: 2023.10.13 14:49:48 EEST
Reason: MoldSign Signature
Location: Moldova

Declaration of Conformity HP PTA Balloon Catheter	File No:JCQ-T-13-01-1 Rev. No:03

Annex 1: Product Model

Catheter Length (cm)	Balloon Diameter (mm)	Balloon Length (mm)									
		20	30	40	60	80	100	120	150	180	200
40	3	ZWH0400300020035B	ZWH0400300030035B	ZWH0400300040035B	ZWH0400300060035B	ZWH0400300080035B	ZWH0400300100035B				
	4	ZWH0400400020035B	ZWH0400400030035B	ZWH0400400040035B	ZWH0400400060035B	ZWH0400400080035B	ZWH0400400100035B				
	5	ZWH0400500020035B	ZWH0400500030035B	ZWH0400500040035B	ZWH0400500060035B	ZWH0400500080035B	ZWH0400500100035B	ZWH0400500120035B			
	6	ZWH0400600020035B	ZWH0400600030035B	ZWH0400600040035B	ZWH0400600060035B	ZWH0400600080035B	ZWH0400600100035B	ZWH0400600120035B			
	7	ZWH0400700020035B	ZWH0400700030035B	ZWH0400700040035B	ZWH0400700060035B	ZWH0400700080035B	ZWH0400700100035B				
	8	ZWH0400800020035B	ZWH0400800030035B	ZWH0400800040035B	ZWH0400800060035B	ZWH0400800080035B	ZWH0400800100035B				
	9	ZWH0400900020035B	ZWH0400900030035B	ZWH0400900040035B	ZWH0400900060035B	ZWH0400900080035B					
	10	ZWH0401000020035B	ZWH0401000030035B	ZWH0401000040035B	ZWH0401000060035B	ZWH0401000080035B					
75	3	ZWH0750300020035B	ZWH0750300030035B	ZWH0750300040035B	ZWH0750300060035B	ZWH0750300080035B	ZWH0750300100035B	ZWH0750300120035B	ZWH0750300150035B	ZWH0750300180035B	ZWH0750300200035B
	4	ZWH0750400020035B	ZWH0750400030035B	ZWH0750400040035B	ZWH0750400060035B	ZWH0750400080035B	ZWH0750400100035B	ZWH0750400120035B	ZWH0750400150035B	ZWH0750400180035B	ZWH0750400200035B
	5	ZWH0750500020035B	ZWH0750500030035B	ZWH0750500040035B	ZWH0750500060035B	ZWH0750500080035B	ZWH0750500100035B	ZWH0750500120035B	ZWH0750500150035B	ZWH0750500180035B	ZWH0750500200035B
	6	ZWH0750600020035B	ZWH0750600030035B	ZWH0750600040035B	ZWH0750600060035B	ZWH0750600080035B	ZWH0750600100035B	ZWH0750600120035B	ZWH0750600150035B	ZWH0750600180035B	ZWH0750600200035B
	7	ZWH0750700020035B	ZWH0750700030035B	ZWH0750700040035B	ZWH0750700060035B	ZWH0750700080035B	ZWH0750700100035B	ZWH0750700120035B	ZWH0750700150035B	ZWH0750700180035B	ZWH0750700200035B
	8	ZWH0750800020035B	ZWH0750800030035B	ZWH0750800040035B	ZWH0750800060035B	ZWH0750800080035B	ZWH0750800100035B	ZWH0750800120035B	ZWH0750800150035B	ZWH0750800180035B	ZWH0750800200035B
	9	ZWH0750900020035B	ZWH0750900030035B	ZWH0750900040035B	ZWH0750900060035B	ZWH0750900080035B					
	10	ZWH0751000020035B	ZWH0751000030035B	ZWH0751000040035B	ZWH0751000060035B	ZWH0751000080035B					
135	3	ZWH1350300020035B	ZWH1350300030035B	ZWH1350300040035B	ZWH1350300060035B	ZWH1350300080035B	ZWH1350300100035B	ZWH1350300120035B	ZWH1350300150035B	ZWH1350300180035B	ZWH1350300200035B
	4	ZWH1350400020035B	ZWH1350400030035B	ZWH1350400040035B	ZWH1350400060035B	ZWH1350400080035B	ZWH1350400100035B	ZWH1350400120035B	ZWH1350400150035B	ZWH1350400180035B	ZWH1350400200035B
	5	ZWH1350500020035B	ZWH1350500030035B	ZWH1350500040035B	ZWH1350500060035B	ZWH1350500080035B	ZWH1350500100035B	ZWH1350500120035B	ZWH1350500150035B	ZWH1350500180035B	ZWH1350500200035B
	6	ZWH1350600020035B	ZWH1350600030035B	ZWH1350600040035B	ZWH1350600060035B	ZWH1350600080035B	ZWH1350600100035B	ZWH1350600120035B	ZWH1350600150035B	ZWH1350600180035B	ZWH1350600200035B
	7	ZWH1350700020035B	ZWH1350700030035B	ZWH1350700040035B	ZWH1350700060035B	ZWH1350700080035B	ZWH1350700100035B	ZWH1350700120035B	ZWH1350700150035B	ZWH1350700180035B	ZWH1350700200035B
	8	ZWH1350800020035B	ZWH1350800030035B	ZWH1350800040035B	ZWH1350800060035B	ZWH1350800080035B	ZWH1350800100035B	ZWH1350800120035B	ZWH1350800150035B	ZWH1350800180035B	ZWH1350800200035B
	9	ZWH1350900020035B	ZWH1350900030035B	ZWH1350900040035B	ZWH1350900060035B	ZWH1350900080035B					
	10	ZWH1351000020035B	ZWH1351000030035B	ZWH1351000040035B	ZWH1351000060035B	ZWH1351000080035B					

Annex 2: Standard List

Area	Standard
Catheters	MEDDEV 2.7.1: 2016, Guidelines on medical devices Clinical evaluation A guide for manufacturers and notified bodies
	EN ISO 10555-1:2013/A1:2017, Sterile Single Use Intravascular Catheters—Part 1: General Requirements
	EN ISO 10555-4:2013, Sterile Single Use Intravascular Catheters—Part 4: Balloon Dilatation Catheters
	ISO 80369-7:2021 Small-bore connectors for liquids and gases in healthcare applications —Part 7: Connectors for intravascular or hypodermic applications
Materials	BS EN ISO 10993-1:2020, Biological Evaluation of Medical Devices, Part 1: Evaluation and testing
	BS ISO 10993-4:2017, Biological Evaluation of Medical Devices: Part 4-Selection of tests for interaction with blood
	BS EN ISO 10993-5:2009, Biological Evaluation of Medical Devices: Part 5-Tests for In Vitro Cytotoxicity
	BS EN ISO 10993-10:2013, Biological Evaluation of Medical Devices: Part 10-Tests for irritation and sensitization
	EN ISO 10993-11:2018, Biological Evaluation of Medical Devices: Part 11-Tests for systemic toxicity
	BS EN ISO 10993-12:2021, Biological Evaluation of Medical Devices: Part 12-Sample Preparation and Reference Materials
	BS EN ISO 14644-1:2015, Cleanrooms and associated controlled environments-Part 1 Classification of air cleanliness
Testing	ASTM D4169-2016, Standard Practice for Performance Testing of Shipping Containers and Systems
	ASTM F1140/F1140M - 13(2020)e1, standard test methods for internal pressurization failure resistance of unrestrained packages
	ISTA 2 Series:2011, Pertial simulation performance test procedure
Sterilization	BS EN ISO 10993-7:2008, Biological Evaluation of Medical Devices: Part 7-Ehylene Oxide Sterilization Residuals
	BS EN ISO 11135:2014/A1:2019, Sterilization of heath care products-Ethylene oxide-Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.
	EN ISO 11737-1:2018/A1:2021, Sterilization of medical devices-Microbiological methods-Part 1: Determination of population of microorganisms on products
	EN 1422:2014, Sterilizers for medical purposes-Ethylene oxide sterilizers-Requirements and test methods

Hazard Evaluation	BS EN ISO 14971:2019, Medical Devices – Application of Risk Management to Medical Devices
Quality	BS EN ISO 13485:2016, Medical Devices—Quality Management Systems –Requirements for Regulatory Requirement
Clinical	BS EN ISO 14155:2020 Clinical investigation of medical devices for human subjects-part 1:General requirements
Labeling & IFU's	EN ISO 15223-1:2016, Medical devices—Symbols to be used with medical device labels, labeling and information to be supplied –Part 1: General requirements
	BS EN 1041:2008+A1:2013, Information supplied by the manufacturer of medical devices
Packaging	EN ISO 11607-1:2020, Packaging for Terminally Sterilized Medical Devices—Part 1: Requirements for materials, sterile barrier systems and packaging systems
	EN ISO 11607-2:2020 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
	ISTA 2A, Partial Simulation Performance Test Procedure: Packaged Products 150lb or Less