

## Jade PTA Over-The-Wire Balloon Dilatation Catheter Phthalates Free Declaration

To Whom It May Concern,

OrbusNeich Medical (Shenzhen) Co., Ltd, hereby declares that the Jade PTA Over-The-Wire does not contain phthalates as defined in the REGULATION (EU) 2017/745 of 5 April 2017 concerning medical devices. Neither the device is intended to administer and/or remove medicines, body liquids or other substances to or from the body, nor the device is intended for transport and storage of such body fluids or substances, contain phthalates.

If you require any additional information regarding this matter, please don't hesitate to contact us.

Sincerely,



Daniel Zhang

Director, Global regulatory

Date: Sep 21, 2021

