EU DECLARATION OF CONFORMITY

Name and address of the manufacturer: /	**Ningbo Transo-Medical Co., Ltd.** **Room 1608, No.18 Diamond Commercial plaza, No.409 Jiang'an Road, Jiangbei District, Ningbo City, Zhejiang Province, P.R. China**
Registered trade name or mark:/	**N.A.**
Single Registration No:/	**CN-MF-000009687**
EU Authorized Representative:/	**Caretechion GmbH** **Niederrheinstr. 71, 40474 Duesseldorf, Germany** **info@caretechion.de** **SRN: DE-AR-000005946**

We declare under our sole responsibility that

Name of the medical device: /	**Quick Splint**
Product code:/	**TM1918** **UMDNS Code: 13681, Splints** **EMDN Code: M03050299**
Intended purpose：/	**Inflatable Quick Splint is used to immobilize broken or injured limbs. This system is specially indicated to limit all movements during transportation and therefore enhances patient comfort and exerts a uniform pressure around the injury to control bleeding. Quick Splint material permit the X ray procedures and therefore can remain in position throughout the X ray hence minimizing the patient discomfort.**
Basic UDI-DI:/	**697461841TM1918KS**
of class: /	**Rule 1, Class I** According to Annex VIII of Regulation (EU) 2017/745 /
Conformity assessment procedure:/	**Declare the conformity of the abovementioned products by issuing this EU Declaration of Conformity after drawing up the technical documentation set out in Annexes II and III of Regulation (EU) 2017/745 /** According to Article 52(7) of Regulation (EU) 2017/745 /
CS reference: /	**EN ISO 15223-1-2016; EN ISO 14971-2019;** **EN ISO 10993-1:2009/AC:2010; EN ISO 10993-5:2009;** **EN ISO 10993-10:2013**

Meets the provisions of the Regulation EU 2017/745(MDR) which apply to it. The declaration is valid in connection with the "final inspection report" of the device. /

Aug 20th, 2021	Chenyun Ye, QM Department
Ort, Datum / Place, date / Lieu, date / Luogo, data	Name und Funktion / Name and function / Nom et fonction / Nome e funzione