

EC DECLARATION OF CONFORMITY

Name and address of the manufacturer: / **Xinxiang Huaxi Sanitary Materials Co.,Ltd.
Dinglun Industrial Zone Changyuan, Xinxiang 453400 Henan
China.**

Registered trade name or mark:/ **Weian**

EC Authorized Representative:/ **Caretechion GmbH
Niederrheinstr 71,40474 Duesseldorf, Germany**

We declare under our sole responsibility that

Name of the medical device: / **Disposable Surgical Face Masks (Type IIR)**

Product code:/ **UMDNS Code: 12458 (Masks, Surgical)**

Intended purpose: / **The Medical Face Masks are intended to be worn to protect against the spread or transmission of infectious germs during surgical interventions in operating theatres and other medical facilities. The main aim is to protect the patient against infectious germs. In addition, in certain situations the wearer should be protected against splashes of potentially contaminated liquids and viable particles.**

Basic UDI-DI:/ **NA**

Trade name:/ **None**

of class: / **Rule1, Class I
according to annex VIII of Regulation (EU) 2017/745 /**

CND code T020601 STANDARD SURGICAL FACE MASKS

CS reference: / **NONE**

Conformity assessment: / **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 /**

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.

Xinxiang April 1, 2020
Ort, Datum / Place, date /
Lieu, date / Luogo, data

Management Representative
Name und Funktion / Name and function /
Nom et fonction / Nome e funzione