

Prüfbericht-Nr.: <i>Test Report No.:</i>	60358333 001	Auftrags-Nr.: <i>Order No.:</i>	190105940
Kunden-Referenz-Nr.: <i>Client Reference No.:</i>	N/A	Auftragsdatum: <i>Order date:</i>	2019-11-29
Auftraggeber: <i>Client:</i>	Xinxiang Huaxi Sanitary Materials Co.,Ltd. Dingluan Industrial Zone, Changyuan, Xinxiang 453400 Henan Province, China		
Prüfgegenstand: <i>Test item:</i>	Disposable Surgical Face Mask		
Bezeichnung / Typ-Nr.: <i>Identification / Type No.:</i>	Elastic Earloop Type		
Auftrags-Inhalt: <i>Order content:</i>	Type test		
Prüfgrundlage: <i>Test specification:</i>	EN 14683:2019+AC:2019		
Wareneingangsdatum: <i>Date of receipt:</i>	2020-02-12		
Prüfmuster-Nr.: <i>Test sample No.:</i>	Engineering sample		
Prüfzeitraum: <i>Testing period:</i>	2020-02-13 to 2020-03-25		
Ort der Prüfung: <i>Place of testing:</i>	TÜV Rheinland (China) Ltd.		
Prüflaboratorium: <i>Testing laboratory:</i>	TÜV Rheinland (China) Ltd.		
Prüfergebnis*: <i>Test result*:</i>	Pass		
geprüft von / tested by: <i>Han Dong</i>		kontrolliert von / reviewed by: <i>Chen Yuhong</i>	
2020-03-26 Han Dong / Project Engineer Datum Name / Stellung Unterschrift <i>Date</i> <i>Name / Position</i> <i>Signature</i>		2020-03-26 Chen Yuhong / Reviewer Datum Name / Stellung Unterschrift <i>Date</i> <i>Name / Position</i> <i>Signature</i>	
Sonstiges / Other: - Attachment 1. Photographic Documentation			
Zustand des Prüfgegenstandes bei Anlieferung: <i>Condition of the test item at delivery:</i>		Prüfmuster vollständig und unbeschädigt <i>Test item complete and undamaged</i>	
* Legende: 1 = sehr gut 2 = gut 3 = befriedigend 4 = ausreichend 5 = mangelhaft P(ass) = entspricht o.g. Prüfgrundlage(n) F(ail) = entspricht nicht o.g. Prüfgrundlage(n) N/A = nicht anwendbar N/T = nicht getestet Legend: 1 = very good 2 = good 3 = satisfactory 4 = sufficient 5 = poor P(ass) = passed a.m. test specification(s) F(ail) = failed a.m. test specification(s) N/A = not applicable N/T = not tested			
Dieser Prüfbericht bezieht sich nur auf das o.g. Prüfmuster und darf ohne Genehmigung der Prüfstelle nicht auszugsweise vervielfältigt werden. Dieser Bericht berechtigt nicht zur Verwendung eines Prüfzeichens. <i>This test report only relates to the a. m. test sample. Without permission of the test center this test report is not permitted to be duplicated in extracts. This test report does not entitle to carry any test mark.</i>			

EC DECLARATION OF CONFORMITY

Name and address of the manufacturer: / Xinxiang Huaxi Sanitary Materials Co.,Ltd.
Dingluan 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, date

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