

Human Med AG Formblatt Konformitätserklärung	Dokumentname: Seite: Rev./Datum: Dok.-Nr./File:	FB 07.32.01 1 von 3 6/ 21.01.2019 FB 07.32.01
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**KONFORMITÄTSEKLRÄUNG / DECLARATION DE CONFORMITE / DECLARATION OF CONFORMITY / DICHIARAZIONE DI CONFORMITÀ**

**Wir / Nous / We / Noi**

**Name des Herstellers/** nom du fabricant/ name of manufacturer/ nome del produttore:

**Human Med AG**

**Adresse des Herstellers/** adresse du fabricant/ address of manufacturer/ indirizzo del produttore:

Wilhelm-Hennemann-Straße 9  
19061 Schwerin  
**Deutschland/** Allemagne/ GERMANY/ Germania

**erklären in alleiniger Verantwortung, dass das Medizinprodukt/** déclarons sous notre propre responsabilité que le dispositif médical/ declare on our own responsibility that the medical device/ dichiariamo sotto propria responsabilità che il dispositivo medico

**Name/** nom/ name/ nome

**WAL Kanüle/** Canules WAL/ WAL cannulae/ Cannule WAL

**Typ /** modèle / model / modello

**REF 503136** (STS Irrigation and aspiration cannula, 4 long suction holes, Ø 4,8mm, l = 30cm) \*

**Losnummer /** no. de lot/ lot number / no. di lotto

XXXXXXXX

**Stückzahl /** quantité / quantity / quantità

XX

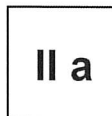
\* Weitere Typen dieses Medizinproduktes werden auf den nachfolgenden Seiten aufgeführt / ultérieur types regardez aux pages suivantes / further types see on the following pages / ulteriori tipi vedono le pagine seguenti

**allen Anforderungen der Richtlinie 93/42/EWG (geändert durch Richtlinie 2007/47/EG) entspricht.**

satisfait aux dispositions applicables de la directive 93/42/CEE (modifiée par Directive 2007/47/CE).  
meets the applicable provisions of the directive 93/42/EEC (amended by Directive 2007/47/EC).  
si attiene alle disposizioni applicabili della direttiva 93/42/CEE (modificata dalla direttiva 2007/47/CE).

**Produktklasse gemäß Anhang IX der Richtlinie 93/42/EWG:**

Classe de produit conformément à l'Annexe de la Directive 93/42/CEE du Conseil :  
Product class according to Annex IX of the Council Directive 93/42/EEC:  
Classe di prodotti secondo l'Allegato IX della Direttiva 93/42/CEE del Consiglio:



**Benannte Stelle/**

**Med Cert GmbH**

Organisme notifié/

Pilatuspool 2, 20355 Hamburg

Notified body/

Deutschland

Organismo notificato:

**CE 0482**

**Verfahren der EG-Konformitätserklärung:**

Procédure relative à la déclaration CE de conformité:

Procedure relating to the EC declaration of conformity:

Procedura per la dichiarazione di conformità CE:

**nach Anhang II ohne Abschnitt 4**

visée à l'annexe II sans application du point 4

set out in Annex II without application of point 4

di cui all'allegato II senza applicazione del punto 4

**Diese Konformitätserklärung bezieht sich auf den aktuellen Reviewstand der technischen Dokumentation und ist bis zum 28.04.2022 gültig.**

La déclaration de conformité présente se réfère à la version actuelle de la documentation technique et est valable jusqu'au 28 avril 2022.

This declaration of conformity refers to the current version of the technical documentation and is valid until 28<sup>th</sup> April 2022.

La presente dichiarazione di conformità si riferisce alla versione attuale della documentazione tecnica ed è valida fino al 28 aprile 2022.

Schwerin, 29.03.2019

**Ort, Datum /** lieu, date / place, date / luogo, data

**Name, Funktion/** nom, fonction/ name, function/ nome, funzione

**Weitere Typen des Medizinproduktes / ultérieur types / further types / ulteriori tipi**

<b>Typ / type ou modèle / type or model / tipo o modello</b>	<b>Losnummer / no. de lot d'échantillons / lot number / no. di lot campione</b>	<b>Stückzahl / nombre d'exemplaires / numbers of items / numero di esemplari</b>
<b>REF 503148</b> (STS Irrigation and aspiration cannula, 4 long suction holes, Ø 4,2mm, l = 30cm)	XXXXXXXXXX	XX
<b>REF 503070</b> (STS Infiltration cannula, Ø 2,5mm, l = 30cm)	XXXXXXXXXX	XX
<b>REF 503089</b> (STS Irrigation and aspiration cannula, 4 long suction holes, Ø 3,5mm, l = 30cm)	XXXXXXXXXX	XX
<b>REF 503204</b> (STS Irrigation and aspiration cannula, 3 long suction holes, Ø 3,8mm, l = 30cm, Subcutaneous)	XXXXXXXXXX	XX
<b>REF 503001</b> (STS Irrigation and aspiration cannula, 4 long suction holes, Ø 3,8mm, l = 30cm)	XXXXXXXXXX	XX
<b>REF 503002</b> (STS Irrigation and aspiration cannula, 4 long suction holes, Ø 3,8mm, l = 30cm, RAPID)	XXXXXXXXXX	XX
<b>REF 503003</b> (STS Infiltration cannula, Ø 3,5mm, l = 30cm)	XXXXXXXXXX	XX
<b>REF 602011</b> (harvest Infiltration cannula, Ø 3,5mm, stainless steel handle)	XXXXXXXXXX	XX
<b>REF 602012</b> (harvest Irrigation and aspiration cannula, Ø 3,5mm, stainless steel handle)	XXXXXXXXXX	XX
<b>REF 580086</b> (Biofill cannula, Ø 3,5mm, l = 15cm, 2 long suction holes, stainless steel handle)	XXXXXXXXXX	XX
<b>REF 580089</b> (Biofill cannula, Ø 3,5mm, l = 15cm, 2 x 2 long suction holes, stainless steel handle)	XXXXXXXXXX	XX
<b>REF 580125</b> (Biofill cannula, Ø 3,8mm, l = 15cm, 2 x 2 long suction holes, stainless steel handle)	XXXXXXXXXX	XX
<b>REF 580107</b> (Biofill infiltration cannula, Ø 2,5mm, l = 15cm, stainless steel handle)	XXXXXXXXXX	XX
<b>REF 581125</b> (Biofill cannula, Ø 3,8mm, l = 15cm, 2 x 2 long suction holes, stainless steel handle, RAPID)	XXXXXXXXXX	XX
<b>REF 580084</b> Biofill cannula, Ø 3,0mm, l = 15cm, 2 long suction holes, stainless steel handle)	XXXXXXXXXX	XX