



Name und Adresse des Herstellers: /
Name and address of the manufacturer:

Ningbo Greatcare Medical Instruments Co., Ltd.
No. 92 Cishanhe Rd., Chunxiao, Beilun,
Ningbo
315830 Zhejiang
China.

SRN

CN-MF-000013677

Name und Adresse des Bevollmächtigten: /
Name and address of the Authorized
Representative:

Greatcare Medical GmbH
Bonner Str. 31
50389
Germany

SRN

SRN: DE-AR-000005587

Wir erklären in alleiniger Verantwortung, dass / We declare under our sole responsibility that /

das Medizinprodukt: /
the medical device:
Intend use

ConSkin Male External Catheter

EMDN code: U070201

The silicone self-adhering male external catheter (sheath) is
designed for the management of male urinary incontinence.

Model:

Siehe den folgenden Anhang I / See the following annex I

Artikelnummer: /

REF No.:

Siehe den folgenden Anhang I / See the following annex I

Basic UDI-DI:

69466801GR-NT-GTF

SRN:

der Klasse: /
of class:

Class I, based on rule 1

Nach Anhang VIII der Verordnung (EU) 2017/745 / according to annex VIII of Regulations (EU) 2017/745

den einschlägigen Bestimmungen der Verordnung (EU) 2017/745 und deren Umsetzungen in nationale Gesetze
entspricht. Die Erklärung gilt in Verbindung mit dem zum Produkt gehörigen „Endprüfprotokoll“. /

meets the provisions of the Regulations (EU) 2017/745 and its transpositions in national laws which apply to it. The
declaration is valid in connection with the "final inspection report" of the device.

Konformitätsbewertungsverfahren: /
Conformity assessment procedure:

**Verordnung (EU) 2017/745 Anhang II & III /
Regulations (EU) 2017/745 Annex II & III**

Anwendbare Norm: /
Applicable Standard:

EN ISO 13485:2016; EN ISO 13485:2016/A11:2021; EN ISO
14971:2019; EN ISO 14971: 2019 / A11: 2021; EN ISO
20417:2021

; EN ISO15223-1: 2021; ISO 10993-1: 2018; ISO 10993-10:
2010; ISO 10993-5: 2009

Registrier-Nr.: /
Registration No.:

N/A

Benannte Stelle: /
Notified Body:

N/A

Ningbo, Oct21, 2023

Ort, Datum / Place, date /
Anhang I / Annex I

Name und Funktion / Name and function /



Description	Model and/or code
Silicone self-Adhering Male External Catheter,Standard type, Size 24mm-S, with tray,1pc/paper plastic Pouch,30pcs/box,300pcs/ctn	GCUEC0014
Silicone self-Adhering Male External Catheter,Standard type, Size 28mm-M, with tray,1pc/paper plastic Pouch,30pcs/box,300pcs/ctn	GCUEC0015
Silicone self-Adhering Male External Catheter,Standard type, Size 31mm-M/L, with tray,1pc/paper plastic Pouch,30pcs/box,300pcs/ctn	GCUEC0016
Silicone self-Adhering Male External Catheter,Standard type, Size 35mm-L, with tray,1pc/paper plastic Pouch,30pcs/box,300pcs/ctn	GCUEC0017
Silicone self-Adhering Male External Catheter,Standard type, Size 40mm-XL, with tray,1pc/paper plastic Pouch,30pcs/box,300pcs/ctn	GCUEC0018