

**EG-KONFORMITÄTSERKLÄRUNG · EC DECLARATION OF CONFORMITY
 DÉCLARATION CE DE CONFORMITÉ · DICHIARAZIONE CE DI CONFORMITÀ**

Name und Adresse des Herstellers: / Zhejiang POCTech Co., Ltd.
 Name and address of the manufacturer: / Add.: No.1633 Hongfeng Road, Building 11-12,
 Nom et adresse du fabricant: / Huzhou City 313000, Zhejiang, China
 Nome e indirizzo del fabbricante:



EC Rep: Prolinx GmbH
 Add: Brehmstr. 56, 40239, Duesseldorf, Germany

Wir erklären in alleiniger Verantwortung, dass / We declare under our sole responsibility that /
 Nous déclarons sous notre propre responsabilité que / Dichiariamo sotto la sola responsabilità che

das Medizinprodukt: / Continuous Glucose Monitoring Systems

the medical device: / (TYPE: CT-100B、CT10、CT14)

le dispositif médical: / UMDNS-CODE:16488

il dispositivo medico:

Continuous Glucose Monitoring Systems consist of a sensor, a transmitter and a receiver/App(Download on personal's mobilephone).

System Model		
Model:CT-100B	Sensor Model	CT-100
	Transmitter Model	CT-100B
	Receiver model	CT-100BD
	APP	/
Model:CT10	Sensor Model	CT-202
	Transmitter Model	CT-100C10
	Receiver model	CT-100BD
	APP	/
Model:CT14	Sensor Model	CT-202
	Transmitter Model	CT-100C14
	Receiver model	CT-100BD
	APP	/



der Klasse: /
 of class: / **IIb**
 de la classe: /
 di classe:

nach Anhang II der Richtlinie 93/42/EWG / according to annex II of directive 93/42/EEC /
 selon l'annexe II de la directive 93/42/CEE / secondo l'allegato II della direttiva 93/42/CEE

den einschlägigen Bestimmungen der Medizinprodukte-Richtlinie 93/42/EWG und deren Umsetzungen in nationale Gesetze entspricht. /

meets the provisions of the directive 93/42/EEC and its transpositions in national laws which apply to it. /

remplit toutes les exigences de la directive sur les dispositifs médicaux 93/42/CEE et de ses transpositions en droit national qui le concernent. /

soddisfa tutte le disposizioni della direttiva 93/42/CEE e della loro trasposizione nel diritto nazionale che lo riguardano.

Konformitätsbewertungsverfahren: / Directive 93/42/EEC Annex II, excluding section 4
 Conformity assessment procedure: /
 Procédure d'évaluation de la conformité: /
 Procedura di valutazione della conformità:

Registrier-Nr.:

Registration No.:
N°d'enregistrement:
Numero di registrazione:

EC Certificate No:CE 710130
Effective Date:2020-03-01

Benannte Stelle: /
Notified Body: /
Organisme notifié: /
Organismo notificato:

BSI Group The Netherlands B.V.
Say Building, John M. Keynesplein 9,
1066 EP Amsterdam,
The Netherlands.
CE 2797

HuZhou 2021-05-20

Ort, Datum / Place, date /

Lieu, date / Luogo, data

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Name:Ya'nan Surname:Zhang President

Name und Funktion / Name and function /

Nom et fonction / Nome e funzione

