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

Name und Adresse des Herstellers: /
Name and address of the manufacturer: /
Nom et adresse du fabricant: /
Nome e indirizzo del fabbricante:

BOEN HEALTHCARE CO., LTD
Unit 602, International Center, No.535, Shenxu Road,
Suzhou, 215021, Jiangsu, China

Digitally signed by Ceaicovschi Tudor
Date: 2022.12.05 13:08:32 EET
Reason: MoldSign Signature
Location: Moldova

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: /
the medical device: /
le dispositif médical: /
il dispositivo medico:

Blood Collection Needle Holder
UMDNS-Code: [12726]

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

I

nach Anhang VIII, Verordnung (EU) 2017/745 / according to annex VIII, Regulation (EU) 2017/745 /
selon l'annexe VIII, le règlement (UE) 2017/745 / secondo l'allegato VIII, regolamento (UE) 2017/745

erfüllt die Anforderungen der Medizinprodukteverordnung (EU) 2017/745 und deren Umsetzungen in nationale Gesetze entspricht. Die Erklärung gilt in Verbindung mit dem zum Produkt gehörigen „Endprüfprotokoll“. /

meets the requirements of Medical Device Regulation (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. /

répond aux exigences du Règlement sur les dispositifs médicaux (UE) 2017/745 et de ses transpositions en droit national qui le concernent. La déclaration est valable si elle est associée au «rapport de l’inspection finale» du produit. /

soddisfa i requisiti del Regolamento sui dispositivi medici (UE) 2017/745 e della loro trasposizione nel diritto nazionale che lo riguardano. Questa dichiarazione è valida in congiunzione con il “rapporto di ispezione finale” del prodotto

Konformitätsbewertungsverfahren: /
Conformity assessment procedure: /
Procédure d’évaluation de la conformité: /
Procedura di valutazione della conformità:

Verordnung (EU) 2017/745 Anhang II+III
Regulation (EU) 2017/745 Annex II+III
Réglementation (UE) 2017/745 Annexe II+III
Regolamento (UE) 2017/745 Allegato II+III

Registrier-Nr.: /
Registration No.: /
N°d’enregistrement: /
Numero di registrazione:

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

CE

Suzhou, 2021.05.26

Ort, Datum / Place, date /
Lieu, date / Luogo, data

General Manager

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

Declaration of Conformity

Manufacturer ： Shandong Chengwu Medical Products Factory
Address: Southern Part of Hu Xin Road ,Chengwu County,Heze City ,Shandong Province,274200 P.R. China.
European Representative SUNSHINE GLOBAL LTD
FLAT 107,25 INDESCON SQUARE,LONDON,UNITED KINGDOM
Represented by Mr. STROBEL Christophe
Tel: +44 (20)31299469 ， Fax: +44(20)31291964

Product： Disposable venous blood specimen collection needle

Model Code respect to CE Technical File CW-CE/TCF-02 A/0

Classification (MDD, Annex IX)： Class Ⅱa

Conformity Routes: Self declaration of conformity as per terms of MDD93/42/EEC ANNEX V (Production quality assurance)

Identification of Notified Body: SZUTEST CE 2195

SZUTEST TURKEY
İnönü Mah. Kayışdağı Cad. No: 148 Münire Sağ İş Merkezi Kat 3-4
Ataşehir / Istanbul
Phone: +90 216 4694666 (pbx)
Fax: +90 216 4694667
E-Mail: info@szutest.com

We herewith declare that the above-mentioned products meet the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer and the notified body.

DIRECTIVES

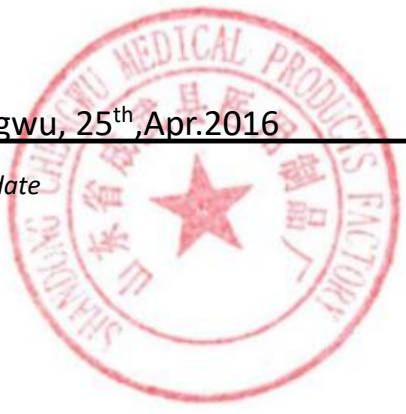
General applicable directives：
Medical Device Directive： COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC).
Standards：
EN ISO13485:2003/AC:2009
EN ISO14971:2009
EN ISO10993-4:2009
EN ISO10993-5:2009
EN ISO10993-7:2008/AC:2009
EN ISO10993-10:2010
EN ISO10993-11:2009
EN980:2008
EN1041:2008
EN ISO 11135-1: 2007
ISO14644-1:1999
ENISO11737-1:2006/AC:2009
ENISO11737-2:2009
EN ISO14155-1:2011
EN ISO 11607-1 :2009
EN ISO 11607-2:2006

All applicable harmonized Standards (published in the Official Journal of the European Communities)

Certificate No.： 2195-MED-1532001

Issue date: 2016.3.12

Expiry date: 2021.3.12



Chengwu, 25th,Apr.2016 Wang jicun

Place ,date *Legally binding signature, Function*