Übereinstimmungserklärung
Statement of Conformity

Hiermit wird bestätigt, dass die Produkte der
It is hereby confirmed that the products of

Ossenberg GmbH
Kanalstraße 79
48432 Rheine
Deutschland

identisch mit denen der von
are identical with those of

HEBEI Healthplus Medical Device Co., Ltd.
No. 1, Chuangye Street, Southwest Industrial District,
Matou Ecological Industry Park, Handan City
Hebei, 056046
China

gelieferten Artikel sind.
deliveres articles.

Artikel-Nr. HEBEI Healthplus Medical Device Co., Ltd. article no. HEBEI Healthplus Medical Device Co., Ltd.	**Produktbezeichnung HEBEI Healthplus Medical Device Co., Ltd.** Product name HEBEI Healthplus Medical Device Co., Ltd.	**Artikel-Nr. Ossenberg GmbH** article no. Ossenberg GmbH	**Produktbezeichnung Ossenberg GmbH** Product name Ossenberg GmbH
12G	**Achselstütze** Axillary Crutch	**12G**	**Achselstützen aus Leichtmetall - große Ausführung bis 120 kg** Axilla crutch made of light metal - large version up to 120 kg
12K	**Achselstütze** Axillary Crutch	**12K**	**Achselstützen aus Leichtmetall - kleine Ausführung bis 120 kg** Axilla crutch made of light metal - small version up to 120 kg

Rheine, den 09.01.2024
Ort, Datum / place, date

Dr. Thomas Schreder
Name und Unterschrift Verantwortliche Person / Name and signature PRRC

Healthplus
User Friendly
凯普威 Medical Products

EU Declaration of Conformity

The following description for the medical device,

Device information	*Description*
Registered trade name and address	*HEBEI Healthplus Medical Device Co., Ltd.* *No. 1, Chuangye Street, Southwest Industrial District, Matou Ecological Industry Park, Handan City, Hebei, 056046, China* *Tel:+86-0310-2111888*
Authorized representative	*Y. Sung Handelsvertretung* *Toulouser Allee 9, 40211 Duesseldorf, Germany*
Common device name	*Crutches*
Product and trade name	Healthplus User Friendly 凯普威 Medical Products
UMDNS code	***11063**, Crutches*
GMDN code	***31115**: Axillary Crutch* ***34977**: Walking Aid, One Arm, Crutch*
Single Registration Number (SRN)	Manufacturer: CN-MF-000013062 / Authorized representative: DE-AR-000005142
Basic UDI-DI	***697322200MXCRUTCHD7***
Risk class of the device	*Class I*
Common Specification (CS) references	*Crutches, Underarm Crutches, Axillary Crutches, Height Adjustable Crutches*
Intended purpose (GMDN definition)	*A staff-like mobility aid used to assist a person with a disability to support their weight while walking. The device has one leg, a padded hand support at the level of the user's wrist, and an under-arm (the armpit or axilla) padded platform. The pads are typically made of non-slip material (e.g., rubber, glycerin gel, sheepskin). The device may be adjustable in length and is typically made of wood or metal [e.g., aluminum (Al), titanium (Ti)].*
Conformity assessment procedure performed and identification of the certificates issued by notified body, if applicable	*Quality Management System* *ISO 13485:2016 by NQA* *ISO 9001:2015 by NQA*
Name and identification number of the notified body, if applicable	*ISO 13485, NQA Certificate Number: 35429* *ISO 9001, NQA Certificate Number: 46296*

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Version: V1.0

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that is covered by the present declaration is in conformity with the Medical Device **Regulation 2017/745/EU** and, if applicable, with any other relevant Union legislation that provides for the issuing of this EU declaration of conformity. The device is in conformity with conformity assessment procedure for **Class I devices** that should be carried out, as a general rule, under the sole responsibility of manufacturers in view of the low level of vulnerability associated with such devices. Thus, manufacturers of class I devices, other than custom-made or investigational devices, shall declare the conformity of their products by issuing an EU declaration of conformity referred to in Article 19 "EC declaration of conformity" after drawing up the technical documentation set out in Annexes II and III of the **Regulation**.

For the evaluation regarding Class I device (Risk class in accordance with the Rule 1 set out in Annex VIII of the **Regulation**), the following harmonized standards are applied:

- *EN ISO 14971:2019 Medical devices – Application of Risk Management*
- *EN ISO 15223-1:2021Medical device – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements*
- *EN 62366-1:2015 Medical devices Part 1-- Application of usability engineering to medical devices*

The following Union authorized representative is stated to the declaration:

Y. Sung Handelsvertretung
Toulouser Allee 9, 40211 Duesseldorf, Germany
(Company name / Registered place of business)

The following person is exclusively responsible for the compliance of declaration:

HEBEI Healthplus Medical Device Co., Ltd.
No. 1, Chuangye Street, Southwest Industrial District, Matou Ecological Industry Park, Handan city, Hebei, 056046, China
(Manufacturer's name/ Registered address)

Dickson Su / General Manager		*March 5, 2023*
(Name/Function)	(Legal Signature)	(Date of issue)

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