


## EU Declaration of Conformity

The following description for the medical device,

Device information	Description
Registered trade name and address	<i>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</i>
Authorized representative	<i>Y. Sung Handelsvertretung Duesselthaler Str. 24, 40211 Duesseldorf Germany</i>
Common device name	<i>Rollators</i>
Product and trade name	
UMDNS code	<i>17980, Walker/Chairs, Wheeled</i>
GMDN code	<i>37951: Basic Walker, Foldable</i>
Single Registration Number (SRN)	<i>CN-MF-000013062</i>
Basic UDI-DI	<i>697322200MXROLLATORUQ</i>
Risk class of the device	<i>Class I as defined by rule 1 of Annex VIII of EU 2017/745</i>
Common Specification (CS) references	<i>None</i>
Intended purpose (GMDN definition)	<i>An all- or partially-wheeled mobility aid in the form of a waist-high, foldable or non-foldable framework with handgrips and four or three legs designed to provide a stable support to a person with a disability, a geriatric or an infirm person when standing or ambulating; it may also be used during rehabilitation. It is constructed of lightweight metal, plastic, and rubber materials in the shape of a mobile support structure which the user holds and pushes in front of them as they walk. It is foldable or non-foldable and includes a braking mechanism; it may be width-adjustable and some types may include a seat on which the user can rest.</i>
Conformity assessment procedure performed	<i>The medical devices identified below have followed the conformity assessment procedure as specified in Article 52(7) of EU 2017/745</i>

<p>Product Code</p>	<ul style="list-style-type: none"> <li>• <i>T8TF/45: CNWO0TQNNCVQT"Y K/J "8\$Y J GGN</i></li> <li>• <i>T8DN/45: CNWO0TQNNCVQT"Y K/J "8\$Y J GGN</i></li> <li>• <i>T: TF/45: CNWO0TQNNCVQT"Y K/J ": \$Y J GGN</i></li> <li>• <i>T: DN/45: CNWO0TQNNCVQT"Y K/J ": \$Y J GGN</i></li> <li>• <i>T94: DN/3: CNWO0TQNNCVQT"Y K/J ": \$Y J GGN</i></li> <li>• <i>T94: TF/3: CNWO0TQNNCVQT"Y K/J ": \$Y J GGN</i></li> <li>• <i>FR6SIL-23: ALUM. ROLLATOR WITH 6" WHEEL</i></li> <li>• <i>TW008R-23: ALUM. DELTA WALKER RED COLOR WITH BAG</i></li> <li>• <i>TW008B-23: ALUM. DELTA WALKER BLUE COLOR WITH BAG</i></li> <li>• <i>TW016BF: THREE WHEEL ALUM. ROLLATOR- KD DESIGN- BLUE</i></li> <li>• <i>TW016RF: THREE WHEEL ALUM. ROLLATOR- KD DESIGN- RED</i></li> <li>• <i>TW012B-1-23: ALUM. DELTA WALKER BLUE COLOR WITH BAG/BASKET/TRAY</i></li> <li>• <i>TW012R-1-23: ALUM. DELTA WALKER RED COLOR WITH BAG/BASKET/TRAY "</i></li> <li>• <i>TW020BL-1: STEEL TRI-WALKER</i></li> <li>• <i>TW020RD-1: STEEL TRI-WALKER</i></li> </ul>
---------------------	---

That is covered by the present declaration is in conformity with the Medical Device **Regulation 2017/745/EU** as amended by **2020/561/EU**:

For the evaluation regarding Class I device (Risk class in accordance with the Rule 1 set out in Annex VIII of **EU 2017/745**), the following harmonized standards are applied:

- *EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes*
- *EN ISO 14971:2012 Medical devices – Application of Risk Management*
- *EN ISO 15223-1:2016 Medical device – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements*
- *EN 62366-1:2015 Medical devices Part 1-- Application of usability engineering to medical devices*
- *EN ISO 11199-2: 2005 Walking aids manipulated by both arms — Requirements and test methods — Part 2: Rollators*

---

The following Union authorized representative is stated to the declaration:

*Y. Sung Handelsvertretung*  
*Duesselthaler Str. 24, 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*  
(Name/Function)

  
(Legal Signature)

*March 4, 2022*  
(Date of issue)