


EU Declaration of Conformity

The following description for the medical device,

Model Name: **W05**

Model Reference: **80119**

Device information	Description
Common device name	<i>Rollators</i>
Registered trade name and address	<i>Charming World Inc. 3F-1, No.75, Sec. 3, Bade Road, Songshan District, Taipei City, 10554, Taiwan TEL:+886-2-25703189</i>
Authorized representative	<i>Y. Sung Handelsvertretung Toulouser Allee 9, 40211 Düsseldorf, Deutschland</i>
Product and Trade name	
UMDNS CODE	<i>17630, walkers, wheeled</i>
EU Single Registration Number (SRN)	<i>TW-MF-000013056</i>
GMDN CODE	<i>37951 : Basic Walker, Foldable 31110: Walking Aid</i>
Basic UDI-DI	<i>471336152R3825XT</i>
Risk class of the device	<i>Class I</i>
Common Specification (CS) references	<i>Walker with wheels, Walker/Chairs with wheeled. Rollator with Seat, Foldable Rollator with Seat.</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 the walk. It is foldable or non-foldable and includes a braking mechanism; it may be height-adjustable and some types may include a seat on which the user can rest.</i>

That is covered by the present declaration is in conformity with the EU Medical Device **Regulation 2017/745/EU**. 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 for the above such devices. The 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**.

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

*Charming World Inc.
3F-1, No.75, Sec. 3, Bade Road, Songshan District,
Taipei City, 10554, Taiwan*

(Manufacturer's name/ Registered address)

Lin Ching Hsueh

*Lin, Ching-Hsueh / CEO
April 22, 2024*