



## HONG KY CO., LTD

Lo F9-F10-F11-F12, D3-N4-N5- Road, Nam Tan Uyen Industrial Park (Expansion),  
Uyen Hung Ward, Tan Uyen Town, Binh Duong Province, Viet Nam 72500

Tel : 0274-3639269



# EU Declaration of Conformity

<b>Manufacturers Name:</b>	HONG KY CO., LTD
<b>Manufacturers Address:</b>	Lo F9-F10-F11-F12, D3-N4-N5- Road, Nam Tan Uyen Industrial Park (Expansion), Uyen Hung Ward, Tan Uyen Town, Binh Duong Province, Viet Nam 72500
<b>SRN (Single Registration Number):</b>	VN-MF-000011592
<b>Authorized Representative Name (if applicable):</b>	Y. Sung Handelsvertretung
<b>Authorized Representative Address (if applicable):</b>	Duesselthaler Str. 24, 40211 Duesseldorf Germany
<b>SRN (Single Registration Number):</b>	DE-AR-000005142
<b>Basic UDI-DI:</b>	893620620EB9XXE2
<b>Name of the Device (s):</b>	HOME CARE ELECTRIC BED
<b>The intended purpose of the medical device:</b>	The HOME CARE BED, hereinafter simply called "bed", is designed for disabled or ill people and is suitable also for home care use. The bed was not specifically designed for hospital use.
<b>Classification:</b>	CLASS I
<b>Identification of the certificates issued by notified body :</b>	ISO 13485:2016 b by Intertek ISO 9001:2015 by Intertek DIN EN ISO 14001:2015 by Royal Cert
<b>The relevant harmonised standards used:</b>	ISO 13485: 2016, EN ISO 14971:2019, EN 15223-1:2016, IEC 60601-1:2005, IEC 60601-1-2:2007, IEC 60601-2-52:2009, AMD1:2015, EN 60601-2-52:2010, EN 60601-1-11:2010
<b>Conformity assessment route:</b>	HONG KY CO., LTD uses the following procedures for the CE-labeling of their products according to the Regulation MDR 2017/745: Class I: EU conformity declaration according to Annex VIII.

This declaration of conformity is issued under the sole responsibility of HONG KY CO., LTD. We hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices.



**HONG KY CO., LTD**

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Signed on behalf of Hong Ky:

Place:

Vietnam

Print Name:

Date (dd.mm.yyyy) of issue:

17.10.2021

Job position:

Sales Manager