Declaration of Conformity

Manufacturer's Name	**Caretek (China) Medical PLC**
Manufacture's Address	Xiguakeng, Guanqiao Village, Shilou Town,Panyu District, Guangzhou City, Guangdong Proince,P.R. China 511447
European Representative	**Shanghai International Holding Corp. GmbH (Europe)** **Single Registration Nr.: DE-AR-000000001**
European Representative Address	Eiffestrasse 80, D-20537 Hamburg, Germany
Single Registration Number	CN-MF-000014175
Declaration	Caretek as the manufacturer of the following medical devices, takes sole responsibility and declares conformity with the applicable provisions of Medical Device Regulation (EU) 2017/745 concerning medical devices, by Annexes II and III.
Device Family Name	**Electric Bed**
Product Codes	**M165,M165-KS**
GMDN Number and Term	**34870 Bed, electric**
Basic UDI-DI	697320759EBYW
Product UDI-DI	6973207590015
Risk Class and Rule	Class I, Rule 13 CE
Additional Information	Also complies with the following EU Legislation: EN ISO 15223-1:2016 EN 1041:2008 EN ISO 14971:2012 IEC 60601-1:2005/AMD1:2012 IEC 60601-1-2:2014 IEC 60601-1-6:2010/AMD1:2013 IEC 60601-2-52:2009+AMD1:2015 EN ISO 10993-1:2010+AC:2010 ISO 13485:2016

APPROVED BY	
Title: CQO	Signature:
Name: David Gao	Date: May,13,2022

On behalf of Caretek: Place Guangzhou.

Caretek (China) Medical PLC 凯泰科(中国)医疗器械股份有限公司