EU DECLARATION OF CONFORMITY

The manufacturer:

Company: KARREL Health Solutions S.r.l. SRN: currently unavailable

Address: Via Don Milani, 11 – 42020 Quattro Castella (RE) - Italy

Declares, under its own and exclusive responsibility, that the devices

Universal Series Emergency Trolleys		
CODE	**ID BD/RDM**	**Basic UDI-DI**
K816419	2194519	805969385K81641XXLU
K816419G	2194520	
K816419GX	2194524	
K816419X	2194526	
K816209	2194531	805969385K81620XXL9
K816209G	2194534	
K816209GX	2194537	
K816209X	2194538	
K816220	2194539	805969385K81622XDQ
K816221	2194541	

Krazy Series Emergency Trolleys		
CODE	**ID BD/RDM**	**Basic UDI-DI**
K820210	2194543	805969385K82021XXJR
K820210X	2194544	
K820211	2194597	
K820211X	2194598	
K820212	2194600	
K820212X	2194602	
K820260	2194603	805969385K82026XXKJ
K820260X	2194604	
K820261	2194605	
K820261X	2194606	
K820262	2194607	
K820262X	2194608	

Simple White Series Emergency Trolleys					
CODE	**ID BD/RDM**	**Basic UDI-DI**	**CODE**	**ID BD/RDM**	**Basic UDI-DI**
KSM-EM1	2194610	805969385KSM-EMXXJC	KSTD-EM1	2194613	805969385KSTD-EMXMF
KSM-EM1S	2194611		KSTD-EM2	2194614	
			KSTD-EM3	2194616	

Intended use:
The devices are intended to be used for the transport of medical equipment and to expedite the performance of health services in emergency conditions.
Environment of use: hospital and care facilities.
Personnel intended for the use of the products: healthcare personnel.
The devices cannot be used in a potentially explosive or flammable atmosphere.

Risk class:

Class I (in accordance with Rule 1, Annex VIII of Regulation (EU) 2017/745)

They are in compliance with the following Union legislative acts:

2017/745/EU - Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

The device is subject to the conformity assessment procedure provided for in article 52, section 7 of Regulation 2017/745/EU

Quattro Castella,
21/01/2022

KARREL Health Solutions S.r.l.
IL PRESIDENTE
FRANCIA MARCO