BIEFFE ITALIA s.r.l. weiko®

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ABI 06230 CAB 14910 CIN E
IBAN IT75 E 06230 14 910 000056503302
BIC Swift CRP PIT 2P

DECLARATION OF CONFORMITY

CE

Annex IV - 745/2017 MDR

BIEFFE ITALIA s.r.l.

As manufacturer of the products underneath listed, declare under its own responsibility that the products:

Model Type	Basic UDI-DI
Kart Emergency Compact	**805373671CompactSK**
Kart Emergency Medium	**805373671Medium6Y**
Kart Therapy Compact	**805373671T_Compact7Q**
Kart Therapy Medium	**805373671T_MediumB6**
Kart Pediatric Compact	**805373671P_Compact4U**
Kart Multipurpose Compact	**805373671CC_CompactDB**
Kart Viewer Compact	**805373671V_Compact96**
Kart Monouse Compact	**805373671MonoRX**

leading to the product family:

KART

are in conformity

with the essential requirements of the **745/2017 MDR** as Class I medical devices according to Annex VIII, Chapter III, Rule 1 (one).

Carinaro,13 May 2021

BIEFFE ITALIA S.r.l.
Dr. Flavio Ferrazzano
CEO

Rev.02 – 13 May 2021