

DECLARATION OF CONFORMITY



Annex IV - 745/2017 MDR

BIEFFE ITALIA S.r.l.

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

code KTM212BK000

Kart Therapy Medium

leading to the product family:

KART

BASIC UDI-DI: 805373671T_MediumB6

is 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