

EU DECLARATION OF CONFORMITY

Name of the manufacturer	OFF CARR S.R.L.
Registered place of business	Via dell'Artigianato II, 29 35010 Villa del Conte – PD - Italy
Contact details	049 9325733 - offcarr@offcarr.com
SRN	IT-MF-000024334

THIS EU DECLARATION OF CONFORMITY IS ISSUED UNDER THE SOLE RESPONSIBILITY OF THE MANUFACTURER AND STATES THAT THE DEVICE

Product name	HEKA
Basic UDI-DI	805390484252DS
Product code	HEKA
Italian Health system registration number	2485443
Intended use	The wheelchairs model HEKA are designed to reduce and counterbalance a physical handicap
Risk class	Class I according to Annex VIII MDR (UE) 2017/745
Manufacturer's quality system certificate	ISO 13485:2016 ISO 9001:2015

IS COMPLIANT TO MDR (UE) 2017/745.

All documentation in support of this declaration is filed at manufacturer's facility.

Place and date	Villa del Conte, 04/05/2024
Name and Surname	Daniilo Volpato
Role	General Manager
Signature	