

EC DECLARATION OF CONFORMITY
EU Konformitätserklärung

Manufacturer:	Concourse Assistive Technology Pty Ltd 9 Hamley Road, Mount Kuring-Gai, NSW 2080 Australia.
SRN:	AU-MF-000043364
Authorized Representative:	Sunrise Medical GmbH Kahlbachring 2-4 D-69254 Malsch / Heidelberg
SRN:	DE-AR-000006321
Product name: Produkt Name:	M90 Trade Names: Empulse M90
Basic UDI-DI:	930900193724M90LP
Intended Purpose: Zweckbestimmung	The Empulse M90 is intended to be used to provide power assistance to manual wheelchair users who are limited in their field of activities because of their physical conditions. It is designed to augment or replace the manual propulsion provided by the user, reducing the effort required by the user to propel the wheelchair.

We, Concourse Assistive Technology Pty Ltd, declare under our sole responsibility that the product(s) to which this declaration relates, is a class 1 device, and is in conformity with the requirements of the Regulation (EU) 2017/745 on medical devices

Wir, Concourse Assistive Technology Pty Ltd, erklären in alleiniger Verantwortung, dass das Produkt, auf welches sich diese Erklärung bezieht, ein Klasse 1Gerät ist und dass es den einschlägigen Bestimmungen der Verordnung (EU) 2017/745 über Medizinprodukte entspricht.

Name:	David Mackay	Daniel Giezekamp
Signature: Unterschrift		
Function: Funktion	CEO	Regulatory Person Responsible for Regulate Compliance
Place and date of issue: Ort und Datum der Ausstellung	11/09/2024 9 Hamley Road, Mount Kuring-Gai, NSW 2080 Australia	11/09/2024 9 Hamley Road, Mount Kuring-Gai, NSW 2080 Australia