EC Declaration of Conformity

Manufacturer:

MEDIROL s.r.o., Na Strži 126/4, 140 00 Praha 4, Czech Republic

ID No: 64506592

SRN: CZ-MF-000006450

Name of medical device:

VIVERA MONOBLOC M301

Basic UDI-DI:

GMN 859420773VIVERAM301X9

Intended use:

Medical device for transporting a recumbent patient inside and outside an ambulance

Risk class of a medical device according to Annex VIII, Regulation of the European Parliament (EU) 2017/745 on medical devices, Rule 1, as amended:

Class I

We declare on our own responsibility that the characteristics of the said product meet the essential requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices and further declare that the said product meets the requirements and tests according to the standard ČSN EN 1865-2+A1:2015, ČSN EN 1865- 3+A1:2015, ČSN EN 1789:2021, ČSN EN 60601-1 ed.2:2007, ČSN EN 60601-1-2 ed.3:2016, ČSN EN 60601-1-6 ed.3:2010, ČSN EN 60529:1993 and EHK OSN 10/06.

The medical device is safe, effective and suitable under conditions of normal use for its intended purpose.

Ing. David Ryska
Managing Director
MEDIROL s.r.o.

Release date: 26th May 2021

CE