XENIOS | A FRESENIUS MEDICAL CARE COMPANY

EU Declaration of Conformity

according to the Regulation (EU) 2017/745 on Medical Devices (MDR), Annex IV

We, the manufacturer

Xenios AG
Im Zukunftspark 1
74076 Heilbronn
Deutschland
SRN: DE-MF-000006233

declare herewith under our sole responsibility

that the in the category

Holder (ACCH)
Basis UDI DI: 4057224-0000-0000-ACCH-Y2

following medical devices include

Holder for Back up Pump Drive Ref. No. 38350411

of risk class

I (according to rule 1 set out in annex VIII of Regulation (EU) 2017/745)

CE-marked with

CE

to which this declaration relates,
meet(s) all the provisions of Regulation (EU) 2017/745 of the European Parliament and of the Council on Medical Devices which apply to it and be carried out according to the Quality Management System EN ISO 13485.

This declaration of conformity is valid latest until June 7th 2026.

Heilbronn, June 11, 2021

i.V.
Thomas-Helge Junesch
Person Responsible for regulatory compliance
Xenios AG

Dr. Peter Schenck
Head of Regulatory Affairs
Xenios AG