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	**Xenios compact holder** **Ref. Nr. 30000145**
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 11th 2026.

Heilbronn, June 11th, 2021

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

P. Schenck
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