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Declaration of Conformity

Applicable Council Directives	IVDD 98/79/EC
Standard to which conformity is declared	EN ISO 15197:2015 & EN ISO 13485:2016
Classification (IVDD 98/79/EC)	Annex II, list B, Self-Testing
Conformity assessment Route	Annex IV excluding (4,6) of the IVDD 98\79\EC
Product Name	Multicare In- Meter, strips and controls for Determination of Glucose, cholesterol and triglycerides in whole blood.
Manufacturer name	Biochemical Systems International S.p.A.
Manufacturer address	Loc Palazzo del Pero 23 52100- Arezzo – ITALY
Notified body	DEKRA CERTIFICATION B.V.

Certificate number 2094844CE03. Issued for the first time: 13 July 2012. Reissued: 11 March 2022. Revision date: 11 March 2022.

We, the undersigned, hereby declare, under our sole responsibility, that the above-mentioned products conform to the specified Directive and Standards. All supporting documents are retained at the premises of the manufacturer.

Arezzo, 11 March 2022

Luigi Cipolleschi
Quality Assurance Manager

