

Declaration of Conformity

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| 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 IVDD 98\79\EC |
| Product Name | LUX- Meter, strips and controls for Determination of Glucose, Cholesterol, Triglycerides, HDL, (LDL calculated) and hemoglobin 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

