

DOC-MA0236	Smart Check EU Declaration of Conformance			
Issued by: Quality		Effective Date: 6/17/2025	Rev. B	Pg. 1 of 1
Approved: 6/17/2025 9:56 AM - Darryl Zitting		Approved: 6/17/2025 9:51 AM - Brent Weight, Management Rep		

EU DECLARATION OF CONFORMITY

1. **Manufacturer:** Life Spark Medical LLC, 2430 W 350 N, Hurricane, UT 84737
2. **Responsibility:** This declaration of conformity is issued under the sole responsibility of the manufacturer, Life Spark Medical LLC
3. **Object of the declaration:** Smart Check Analyzer, with
 - Ref. No. MA0236FR French accompanying documents.
 - Ref. No. MA0236EN English accompanying documents.
4. **Regulations:** The object of the declaration described in point 4 is in conformity with the relevant Union harmonisation legislation: See Table 1.

Table 1: EU directives and harmonized standards		
Directive	Description	Harmonized Standards
Regulation (EU) 2023/988	General Product Safety (GPSD)	EN standard EN 60601-1: General Safety Standard
Directive 2014/30/EU	Electromagnetic compatibility (EMC)	EN 60601-1-2:2015: Electromagnetic compatibility for medical devices
Directive 2011/65/EU	Restriction of the use of certain hazardous substances (RoHS)	EN IEC 63000: Documentation for the evaluation of electrical and electronic equipment for RoHS compliance
Directive 2012/19/EU	Waste Electrical and Electronic Equipment (WEEE)	EN 50419:2006: Marking requirements for WEEE compliance.
Regulation (EC) No 1907/2006	Chemical substances (REACH)	No specific harmonized standard.

5. Signed for and on behalf of: Life Spark Medical, 2430W 350N, Hurricane, UT 84737.



Darryl Zitting, 6/17/2025