DECLARATION OF CONFORMITY
(According to Annex IV)

Manufacturer:	**IRON DUCK (SRN: US-MF-000016043)** 102 1st Ave. | Chicopee, MA 01022, United States of America
EU Authorized Representative:	**RQMIS AREU SLU (ES-AR-000002139)** Av Diagonal 409, Barcelona 08008, Spain
Medical Device Classification: (MDR EU 2017/745 Annex VIII, Chapter III, 4.1)	**Class I** (Rule 1)
Conformity Assessment Route:	Annex II and Annex III
GMDN Code:	**13673**
GMDN Description:	**Spine board**
Status	**Self-certified**
Device description:	1: Lifeguard Spineboard mit Speed-Clip ohne Gurte, Schwarz - UDI-DI: 00860007743221 N5 0300-B 35719-P-B 2: Lifeguard spineboard mit Speed-Clip Pin ohne Gurte, olivegrune – UDI-DI: 00860007743238 N5 0300-TG 35719-P-OD 3: Lifeguard Spineboard mlt Speed-Clip ohne Gurte, gelb – UDI-DI: 00860007743214 N5 0300 35719-P-FY 4: Lifeguard Spineboard, gelb, ohne Fixiergurte-N5 0100Y – UDI-DI: 00860007743207 35719-FY
Basic UDI:	**0860007743201N50100YK8**

Iron Duck Inc declares, under its own responsibility, that the above mentioned medical device is conforming to the GSPR of the Medical Device Regulation EU 2017/45 and conforming to the applicable rules of product and process. Technical File and supporting documentation are retained under the premises of the Manufacturer at disposition of the Competent Authorities. The manufacturer is the only responsible for this Declaration of Conformity. Iron Duck Inc has developed an internal procedure for the vigilance system of the medical devices according to MDR EU 2017/45. Iron Duck complies with the requested harmonised norms and standards for marketing their products in the EU and US*.

Validity of this declaration of conformity: 365 days from the date of issue

Chicopee,

Signature: :

Date: Jan 15, 2024

*List of International Standards

Reference	Title
ISO 14971	Medical devices- Application of risk management to medical devices
(EU) 2017/745	Medical devices regulation (MDR)
GSPR-1	General Safety and Performance Requirements – Performance and Safety
GSPR-7	General Safety and Performance Requirements – Packaging, transport, storage
ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purposes
ISO 9001	QUALITY MANAGEMENT SYSTEMS
ASTM D638	Standard Test Methods for Tensile Properties of Plastics (2014)
ASTM F1877	Standard Practice for Characterization of Particles (2005)
UNI EN 1865-1	Directives for stretchers and other patient transport equipment on ambulances