



Declaration of Conformance

Device Group: Lerman Non-Invasive Halo

Manufacturer: Trulife 26284 Twelve Trees Lane NW Poulsbo WA 98370, USA

SRN: US-MF-000009657

Classification: Class I

Basic UDI-DI: 00645517Cervical72

Intended Purpose: The Non-Invasive Halo is intended for cervical spine immobilization of stable, non-displaced or minimally displaced fractures.

Product Code	Product Name	UDI	UMDNS Code
A37802	Lerman Non-Invasive Halo	645517325002	17-909

Trulife hereby declares and ensures with sole responsibility, that the above mentioned, Class I, Medical Device(s) meet the provisions of the Regulation MDR 2017/745 for medical devices which apply to them.

The obligations laid down in Annex II and Annex III according to Regulation MDR 2017/745 for CE labelling have been fulfilled.

Trulife has appointed Medical Device Safety Service (MDSS) of Hannover, Germany to act as our EU authorized representative. They may be contacted at:

MDSS GmbH
Schiffgraben 41
30175 Hannover
Germany
Phone (+49) 511 6262 8630
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Reviewed by:

Chris Henry
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Poulsbo WA, USA

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Date (YYYY-MM-DD)