



Declaration of Conformance

Device Group: Orthoses, Back

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

Product Name: See Below

Description: Class I Orthotic Devices, 510K exempt

Product Code(s): Various, See below

Intended Purpose: The Lerman Minerva is intended to support and stabilize C2-T3 stable fractures, muscular/ligamentous injury, degenerative joint disease, cervical pain, and nerve impingement.

The following product codes fall under Basic UDI-DI: **00645517Cervical72**

Product Code	Product Name	UDI	FDA Code	UMDNS Code
A193PED	LERMAN MINERVA PEDIATRIC	645517848891	IQF	17-909
A193REG	LERMAN MINERVA REGULAR	645517848877	IQF	17-909
A193SM	LERMAN MINERVA SMALL	645517848884	IQF	17-909
A193PED-CHIN-MR	CHIN ASSY PED MINERVA	645517852560	IQF	17-909
A193PED-OCPT-MR	OCCIPITAL ASSY PED MINERVA	645517852584	IQF	17-909
A193REG-CHIN-MR	CHIN ASSY REG MINERVA	645517852607	IQF	17-909
A193REG-OCPT-MR	OCCIPITAL ASSY REG MINERVA	645517852621	IQF	17-909
A193SM-CHIN-MR	CHIN ASSY SM MINERVA	645517852645	IQF	17-909
A193SM-OCPT-MR	OCCIPITAL ASSY SM MINERVA	645517852669	IQF	17-909
O10901	MINERVA PAD SET RG	645517323831	IQF	17-909
O10902	MINERVA PAD SET SM	645517323848	IQF	17-909
O10927	PAD CHIN RG MINERVA	645517510729	IQF	17-909
O10928	PAD OCCIP RG MINERVA	645517510743	IQF	17-909
O10931	PAD CHIN SM MINERVA	645517323886	IQF	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
FAX (+49) -511-6262 8633

Reviewed by:

A handwritten signature in blue ink, appearing to read "Chris Henry".

Chris Henry
R&D Manager
Poulsbo WA, USA

2021-07-02

Date (YYYY-MM-DD)