



# EU DECLARATION OF CONFORMITY

MEDICAL DEVICE REGULATION (EU) 2017/745 and saa

THE MANUFACTURER Harken Inc.  
 REGISTERED OFFICE N15W24983 Bluemound Rd, Pewaukee, WI 53072-4974 – USA  
 AUTHORIZED REPRESENTATIVE Harken Italy S.p.A.  
 REGISTERED OFFICE Via Marco Biagi, 14  
 22070 Limido Comasco (CO) – Italy

## DECLARES UNDER HIS SOLE RESPONSIBILITY THAT THE DEVICE

NAME Professional series litters

BASIC UDI-DI	PRODUCT COMMERCIAL CODE	PRODUCT COMMERCIAL NAME
0850038937CRCRSLPSSPG	CRC-RSL-PSS1	Professional Series Litters - One Piece Tapered Stainless Steel
	CRC-RSL-PSS2	Professional Series Litters - Two Piece Tapered Stainless Steel
	CRC-RSL-PSSR-1	Professional Series Litters - One Piece Rectangular Stainless Steel
	CRC-RSL-PSSR-2	Professional Series Litters - Two Piece Rectangular Stainless Steel
0850038937CRCRSLPT2Q	CRC-RSL-PT1	Professional Series Litters - One Piece Tapered Titanium
	CRC-RSL-PT2	Professional Series Litters - Two Piece Tapered Titanium
	CRC-RSL-PTR-1	Professional Series Litters - One Piece Rectangular Titanium
	CRC-RSL-PTR-2	Professional Series Litters - Two Piece Rectangular Titanium Litter

INTENDED USE

The medical device family Professional Series Litters is design for the recovery and transport of patients They can be used for rescue operations in those cases where it is necessary to protect patients from side impacts, where it is not possible to intervene with normal transport equipment.

## SATISFIES THE REQUIREMENTS OF THE FOLLOWING REGULATIONS

MEDICAL DEVICE REGULATION (EU) 2017/745 AND SAA European Medical Device Regulation

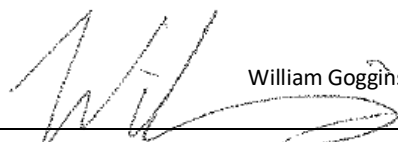
## OTHER INFORMATION

CLASSIFICATION Class I according to Annex VIII, rule 1 of MDR (EU) 2017/745

Date

Pewaukee, 01/01/2023

CEO



William Goggins