Declaration of Conformity

This European Declaration of Conformity is issued under the sole responsibility of the manufacturer.

MANUFACTURER		
Name of Company	**Address**	**SRN**
DUPACO, INC.	4144 Avenida de la Plata Oceanside, CA 92056, USA	US-MF-000003390

AUTHORIZED REPRESENTATIVE			
Name of Company	**Address**	**SRN**	**Telephone/fax/email**
Emergo Europe	Westervoortsedijk 60 6827 AT Arnhem The Netherlands	NL-AR-000000116	+31.70.345.8570 - phone EmergoEurope@ul.com

PRODUCT IDENTIFICATION			
Product Name	**Product Code (Model #) / Description**	**UDI-DI (GTIN)**	**Basic UDI-DI (GMN)**
ProneView Protective Helmet System	D28501CE / PROTECTIVE HELMET Pack	10850017419206	0850017419PRONEVIEWNW
	D28502CE/ ADJUSTABLE PROTECTIVE HELMET Pack	10850017419213	0850017419PRONEVIEWNW
	D28503CE/ LARGE CUSHION 10 PACK	10850017419121	0850017419PRONEVIEWNW
	D28505CE/ MEDIUM CUSHION 10 PACK	10850017419114	0850017419PRONEVIEWNW
	D28507CE/ SMALL CUSHION 10 PACK	10850017419107	0850017419PRONEVIEWNW
	D28510CE/ ADJUSTABLE PROTECTIVE HELMET AND MIRROR SYS Kit	00850017419353	0850017419PRONEVIEWNW
	D28520CE/ MIRROR PLATFORM Pack	10850017419220	0850017419PRONEVIEWNW
	D28520DE/ MIRROR PLATFORM, DE Pack	10850017419237	0850017419PRONEVIEWNW
	D28580CE/ MIRROR PLATFORM WITH POST HOLES Pack	10850017419244	0850017419PRONEVIEWNW
	D28590CE/ ADJUSTABLE MIRROR Pack	10850017419251	0850017419PRONEVIEWNW
	D28590DE/ ADJUSTABLE MIRROR, DE Pack	10850017419268	0850017419PRONEVIEWNW
	D28700CE/ TABLE PLATFORM	10850017419275	0850017419PRONEVIEWNW
	D28705CE/ TABLE PLATFORMWITH PROTECTIVE HELMET Kit	00850017419346	0850017419PRONEVIEWNW

Intended Purpose	Photo
Designed to support the head during prone position surgical procedures	 

RISK CLASS FOR MEDICAL DEVICES	
Device Classification	**Rationale**
Class 1, Rule 1	Rules 2-4 do not apply to these Class 1 Non-Invasive Devices. Reference MDR (EU) 2017/745, Annex VIII, Chapter III, Section 4.1

DUPACO, INC. declares that the above-mentioned product (ProneView Protective Helmet System) meets the provision of MDR (EU) 2017/745.

COMPANY REPRESENTATIVE:
NAME: Dustin Lewis
TITLE: Quality Assurance Manager
PLACE: 4144 Avenida de la Plata
Oceanside, CA 92056, USA

SIGNATURE: Dustin Lewis

DATE:

Digitally signed by Dustin Lewis
DN: cn=Dustin Lewis, o=Dupaco, Inc., ou=Quality Assurance, email=dlewis@dupacoinc.com, c=US
Date: 2025.05.28 10:52:39 -07'00'