



Declaration of Conformity

Name & Address of the Manufacturer: Trulife Limited,
Airton Road,
Tallaght,
Dublin 24,
Ireland

Single Registration Number: IE-MF-000003108

Competent Authority: The Health Products Regulatory Authority,
Block A, Kevin O'Malley House,
Earlsfort Centre,
Earlsfort Terrace,
Dublin 2, D02 XP77
Ireland

Name of Device(s): Azure, Elite, Oasis and Oasis+

Reference Code: See Annex I attached

Basic UDI-DI: 00643293PressurecareDT

Ref: SQM67-2
Rev: 0

Initiated by: R. Holmes 25/01/2023
Approved by: E. Redmond 25/01/2023
Released by: R. Holmes 25/01/2023

Intended Use: Pressurecare products are designed to assist with the distribution of pressure across a larger surface area and assist with supporting patient positioning.

Classification: Class I

Rule: Rule 1 Annex VIII – MDR 2017/745

We hereby declare, under our sole responsibility, that the below product groups are Class I Medical Devices registered in Ireland and are in conformity with the European Medical Device Regulations 2017/745 and relevant standards (See Annex II attached).

Approved by: Rebecca Holmes
Rebecca Holmes
Senior Quality Specialist
(On behalf of Trulife)

Date: 25/01/2023

Place of Issue: Dublin, Ireland

Expiry Date: 25/01/2024

Annex I

Product Code	Name	Description
AZ100	Azure Head Protector	260x250x50mm
AZ200	Azure Arm Protector Short	330x140x30mm
AZ201	Azure Arm Protector Long	460x180x35mm
AZ300	Azure Sacral Protector Small	400x380x25mm
AZ301	Azure Sacral Protector Large	450x445x30mm
AZ400	Azure Leg Protector	515x180x40mm
AZ401	Azure Heel Protectors	190x175x30mm
AZ410	Azure Crutch Stirrups Pad	370x205x25mm
AZ500	Azure Universal Positioner	425x155x60mm
AZ610	Azure Universal Table Pad	520x520x10mm
AZ611	Azure 3/4 Length Table Pad	1150x520x10mm
EL011	Oasis Elite Closed Head Ring Adolescent	140x34mm
EL012	Oasis Elite Closed Head Ring Adult	200x50mm
EL021	Oasis Elite Open Head Ring Adolescent	140x34mm
EL022	Oasis Elite Open Head Ring Adult	200x54mm
EL030	Oasis Elite Universal Table Pad	520x520x30mm
EL031	Oasis Elite 3/4 length Table Pad	1150x520x20mm
EL070	Oasis Elite Armboard Pad Short	400x125x20mm
EL072	Oasis Elite Armboard Pad Long	600x125x20mm
EL130	Oasis Elite Heel Pad (x2)	180x100x70mm
EL141	Oasis Elite Prone Head Rest Large	280x240x140mm
EL142	Oasis Elite Prone Head Rest Medium	273 x 220 x 135mm
EL151	Oasis Elite Supine Head Rest Adult	275x237x90mm
EL152	Oasis Elite Supine Head Rest Adolescent	275x230x65mm
EL210	Oasis Elite Dome Positioner	350x150x75mm
EL214	Oasis Elite Flat Bottom Chest Rolls	300x140x110mm
EL215	Oasis Elite Flat Bottom Chest Rolls	400x140x110mm
EL216	Oasis Elite Flat Bottom Chest Rolls	505x140x110mm
EL217	Oasis Elite Flat Bottom Chest Rolls	405x150x150mm
EL218	Oasis Elite Flat Bottom Chest Rolls	510x150x150mm
EL401	Oasis Elite Contoured Arm/Knee Pad Large	510x155x40mm
EL402	Oasis Elite Arm/Knee Pad	395x140x40mm
EL800	Oasis Elite Lateral Leg Positioner	650x400x230mm
EL900	Oasis Elite Lateral Positioner	720x500x160mm
EL903	Oasis Elite Prone Positioner	610x530x130mm
EL904	Oasis Elite Large Prone Positioner	1115x520x140mm
EL905	Oasis Elite Prone Positioning System	675x500x100mm
EL906	Upper Left Section/Lower Right Section	275x250x100mm
EL907	Upper Right Section/Lower Left Section	275x250x100mm
EL908	Mid Left Section/Mid Right Section	125x250x100mm
EL913	Lateral Positioning Pad	520x413x230mm
ELP011	Elite Universal Positioner	330x230x50mm
ELP049	Elite Wedge Positioner	250x200x100mm
ELP141	ARDS Prone Headrest Pad (x3)	265x245x170mm

Annex I (cont'd)

Product Code	Name	Description
ELP200	ARDS Prone Pad System	N/A
ELP214	Elite Roll Positioner	120x500mm
ELP215	ARDS Chest Positioning Pad	300x500x171mm
ELP216	ARDS Stomach Positioning Pad	300x500x161mm
ELP217	ARDS Hip Positioning Pad	300x500x81mm
ELP218	ARDS Shin Positioning Pad	310x500x150mm
ELP914	Prone Positioning Pad	480x1014x140mm
ELT015	ET Anti Slip Mat	550x300x5mm
ELT21 (Pair)	ET Shoulder Support	300x165x220mm
ELT22 (Pair)	ET Arm Retainer	235x235x300mm
ELT23 (Pair)	ET L-Bracket	75x40x65mm
ELT24 EU (Pair)	ET Clamp EU	75x40x65mm
ELTS20	Elite Trendelenburg System 20°	N/A
ELTS40	Elite Trendelenburg System 40°	N/A
ELT900	Elite Trendelenburg Positioner	830x550x90mm
OA010	Oasis Closed Head Ring Paediatric	90x20mm
OA011	Oasis Closed Head Ring Adolescent	140x35mm
OA012	Oasis Closed Head Ring Adult	200x45mm
OA020	Oasis Open Head Ring Paediatric	90x22mm
OA021	Oasis Open Head Ring Adolescent	140x35mm
OA022	Oasis Open Head Ring Adult	200x50mm
OA030	Operating Universal Table Pad	520x520x10mm
OA031	Oasis 3/4 Length Table Pad	1150x520x10mm
OA032	Oasis Full Length Table Pad	1800x520x10mm
OA033	Oasis Paediatric Full Length Pad	605x335x10mm
OA036	Oasis Head Section	225x500x10mm
OA037	Oasis Torso Section	990x500x10mm
OA040	Oasis Perineal Table Pads	520x520x10mm
OA050	Oasis Universal Patient Positioners	150x60x40mm
OA051	Oasis Universal Patient Positioners	330x70x50mm
OA052	Oasis Universal Patient Positioners	290x100x60mm
OA053	Oasis Universal Patient Positioners	345x120x70mm
OA061	Oasis Ulnar/Brachial Nerve Protector	460x210x8mm
OA062	Oasis Ulnar/Brachial Nerve Protector Full Length	460x380x8mm
OA070	Oasis Armboard Pads	395x115x10mm
OA071	Oasis Armboard Pads	600x200x10mm
OA072	Oasis Armboard Pads	600x125x10mm
OA090	Oasis Crutch Stirrup Pads (x2)	320x220x10mm
OA091	Oasis Crutch Stirrup Pads (x2)	395x245x10mm
OA092	Oasis Crutch Stirrup Pads (x2)	520x300x10mm
OA094	Oasis Thigh Pad	520x130x10mm
OA100	Oasis Arm Retainer Pad	170x110x18mm
OA101	Oasis Contoured Armboard Pad	510x150x35mm

Annex I (cont'd)

Product Code	Name	Description
OA110	Oasis Patient Positioning Belt	505x85x8mm
OA113	Oasis Extremity Belt	315x45x10mm
OA130	Oasis Heel Pad (x2)	180x100x70mm
OA131-2	Oasis Heel Cups (x2)	105x90x43mm
OA131-36	Oasis Heel Cups Box of 36	105x90x43mm
OA140	Oasis Face Pad	165x80x8mm
OA200	Oasis Heel & Ankle Protector (x2)	250x120x10mm
OA211	Oasis Flat Bottom Chest Rolls	305x95x75mm
OA212	Oasis Flat Bottom Chest Roll	405x95x75mm
OA213	Oasis Flat Bottom Chest Roll	505x92x75mm
OP015	Oasis + Disc (10 disc per box)	200x200x4mm
OP041	Oasis + Universal Profile Pad	520x520x9mm
OP070	Oasis+ Short Arm Pad	395x134x10mm
OP101	Oasis+ Long Arm Pad	500x161x40mm
OP130	Oasis + Heel Pads	151x134x66mm
OP132	Oasis+ Heel Protectors	127x162x71mm
OP151	Oasis + Head and Neck Support	264x220x64mm
TR012	Trendelenburg Headrest	260x200x154mm
CVP01	Clearview Prone Headrest	300x225x175mm
CVF01	Clearview Foam Face Pad (pack of 5)	400x250x25mm

Ref: SQM67-2
Rev: 0

Initiated by: R. Holmes 25/01/2023
Approved by: E. Redmond 25/01/2023
Released by: R. Holmes 25/01/2023

Annex II: Harmonised and other Standards

Applied Standards	Description of Standard
MDR 2017/745	Regulation (EU) 2017/745 of the European Parliament and of the Council, of 5 April 2017, on medical devices
ISO 13485:2016	Medical devices -- Quality management systems -- Requirements for regulatory purposes
ISO 14971:2019	Medical devices. Application of risk management to medical devices
ISO 15223-1 (2021)	Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements Part 2: Symbol development, selection and validation.
ISO 15223-2 (2010)	
ISO 10993-10: (2021)	ISO 10993-10 describes the procedure for the assessment of medical devices and their constituent materials with regard to their potential to produce irritation and skin sensitization.
ISO 10993-1: (2018)	The general principles governing the biological evaluation of medical devices within a risk management process;