

We,

**BSN medical Inc.
5825 Carnegie Blvd.
28209 Charlotte,
USA
(SRN: US-MF-000019174)**

hereby declare under our sole responsibility, that this product family complies with the applicable requirements of the regulation (EU) 2017/745 of the European parliament and of the council on medical devices (MDR).

Product Name:

Dynacast® Prelude

Basic UDI-DI:

4042809400348879Z

Intended purpose:

Refer to regulatory assessment

Conformity assessment route: **Annex II+III**

Classification rule:

1

Classification:

I

The Declaration of Conformity is performed in accordance with the quality management system according to EN ISO 13485, and fulfils the general safety and performance requirements of the regulation (EU) 2017/745.

European Authorized Representative:

**BSN medical GmbH
Schützenstr. 1-3
22761 Hamburg
Germany
(SRN: DE-AR-000005791)**

Declaration of conformity issued: 07.02.2024

Compiled and released:

Charlotte,, 07.02.2024
Dr. Andreas Matthies
Global Regulatory Affairs Director
BSN medical Inc.

Article	Description	REF
47222-00000-04	DYNACAST PRELUDE SINGLE LAYER ORTHO GLASS II 7.5CM X 30CM 1 AR ZH DA NL EN FI FR DE EL IT NO PT ES SV	47222-00
47223-00000-04	DYNACAST PRELUDE SINGLE LAYER ORTHO GLASS II 7.5CM X 40CM 1 AR ZH DA NL EN FI FR DE EL IT NO PT ES SV	47223-00
47224-00000-04	DYNACAST PRELUDE SINGLE LAYER ORTHO GLASS II 10CM X 30CM 1 AR ZH DA NL EN FI FR DE EL IT NO PT ES SV	47224-00
47225-00000-04	DYNACAST PRELUDE SINGLE LAYER ORTHO GLASS II 10CM X 40CM 1 AR ZH DA NL EN FI FR DE EL IT NO PT ES SV	47225-00
47226-00000-04	DYNACAST PRELUDE SINGLE LAYER ORTHO GLASS II 10CM X 76CM 1 AR ZH DA NL EN FI FR DE EL IT NO PT ES SV	47226-00
47227-00000-04	DYNACAST PRELUDE SINGLE LAYER ORTHO GLASS II 12.5CM X 65CM 1 AR ZH DA NL EN FI FR DE EL IT NO PT ES SV	47227-00
47235-00000-04	DYNACAST PRELUDE SINGLE LAYER ORTHO GLASS II 12.5CM X 76CM 1 AR ZH DA NL EN FI FR DE EL IT NO PT ES SV	47235-00
71415-00000-04	DYNACAST PRELUDE SINGLE LAYER ORTHO GLASS II 10CM X 4.6M 1 AR ZH DA NL EN FI FR DE EL IT NO PT ES SV	71415-00
71416-00000-04	DYNACAST PRELUDE SINGLE LAYER ORTHO GLASS II 12.5CM X 4.6M 1 AR ZH DA NL EN FI FR DE EL IT NO PT ES SV	71416-00
71417-00000-04	DYNACAST PRELUDE SINGLE LAYER ORTHO GLASS II 15CM X 4.6M 1 AR ZH DA NL EN FI FR DE EL IT NO PT ES SV	71417-00
71418-00000-04	DYNACAST PRELUDE SINGLE LAYER ORTHO GLASS II 2.5CM X 4.6M 1 AR ZH DA NL EN FI FR DE EL IT NO PT ES SV	71418-00
71419-00000-04	DYNACAST PRELUDE SINGLE LAYER ORTHO GLASS II 20C X 2.3M 1 AR ZH DA NL EN FI FR DE EL IT NO PT ES SV	71419-00
71419-00009-04	DYNACAST PRELUDE 7.5CM X 30CM 1 EN FR PRE-CUT FRANCE	71419-09
71419-00010-04	DYNACAST PRELUDE 10CM X 38CM 1 EN FR	71419-10

Article	Description	REF
	PRE-CUT FRANCE	
71419-00011-04	DYNACAST PRELUDE 10CM X 76CM 1 EN FR PRE-CUT FRANCE	71419-11
71419-00012-04	DYNACAST PRELUDE 12.5CM X 76CM 1 EN FR PRE-CUTFRANCE	71419-12
71419-00015-04	DYNACAST PRELUDE 7.5CM X 30CM 1 EN FR PRE-CUT LPPR	71419-15
71419-00016-04	DYNACAST PRELUDE 10CM X 38CM 1 EN FR PRE-CUT LPPR	71419-16
71419-00017-04	DYNACAST PRELUDE 10CM X 76CM 1 EN FR PRE-CUT LPPR	71419-17
71419-00018-04	DYNACAST PRELUDE 12.5CMX76CM 1 EN FR PRE-CUT LPPR	71419-18
71420-00000-04	DYNACAST PRELUDE SINGLE LAYER ORTHO GLASS II 5CM X 4.6M 1 AR ZH DA NL EN FI FR DE EL IT NO PT ES SV	71420-00
71421-00000-04	DYNACAST PRELUDE SINGLE LAYER ORTHO GLASS II 7.5CM X 4.6M 1 AR ZH DA NL EN FI FR DE EL IT NO PT ES SV	71421-00
72869-00000-04	DYNACAST PRELUDE SINGLE LAYER ORTHO GLASS II 5CM X 25CM 1 AR ZH DA NL EN FI FR DE EL IT NO PT ES SV	72869-00
73418-00000-04	DYNACAST PRELUDE SINGLE LAYER ORTHO GLASS II 15CM X 76CM 1 AR ZH DA NL EN FI FR DE EL IT NO PT ES SV	73418-00