

We,

**BSN medical Inc.  
5825 Carnegie Blvd.  
28209 Charlotte,  
USA  
(SRN: not issued yet)**

hereby declare under our own responsibility, that this product family complies with the applicable regulations 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: **(not defined yet)**  
Intended purpose: **Refer to clinical evaluation**  
Conformity assessment route: **Annex II+III**  
Classification rule: **1**  
Classification: **I**

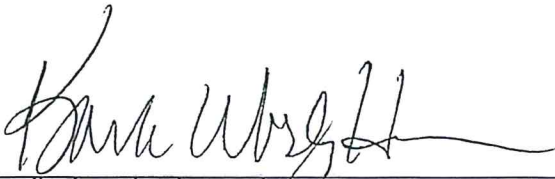
The Declaration of Conformity is performed in accordance with the quality management system according to EN ISO 13485, and fulfils the general safety and performance requirements of the regulation (EU) 2017/745.

**European Authorized Representative:**

**BSN medical GmbH  
Quickbornstrasse 24  
20253 Hamburg  
Germany**

Certificate No 50708-14-00 (EN ISO 13485)

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Compiled and released: \_\_\_\_\_

Charlotte,, 03/03/2020  
Karla Worley-Ham  
Director Regulatory Affairs, LM NA  
BSN medical Inc.

Article	Description	REF
47222-00000-03	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
47223-00000-03	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
47224-00000-03	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
47225-00000-03	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
47226-00000-03	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
47227-00000-03	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
47235-00000-03	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
71415-00000-03	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
71416-00000-03	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
71417-00000-03	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
71418-00000-03	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
71419-00000-03	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
71419-00009-01	DYNACAST PRELUDE 7.5CM X 30CM 1 EN FR PRE-CUT FRANCE	71419-09
71419-00010-01	DYNACAST PRELUDE 10CM X 38CM 1 EN FR	71419-10

Article	Description	REF
	PRE-CUT FRANCE	
71419-00011-01	DYNACAST PRELUDE 10CM X 76CM 1 EN FR PRE-CUT FRANCE	71419-11
71419-00012-01	DYNACAST PRELUDE 12.5CM X 76CM 1 EN FR PRE-CUTFRANCE	71419-12
71419-00015-01	DYNACAST PRELUDE 7.5CM X 30CM 1 EN FR PRE-CUT LPPR	71419-15
71419-00016-01	DYNACAST PRELUDE 10CM X 38CM 1 EN FR PRE-CUT LPPR	71419-16
71419-00017-01	DYNACAST PRELUDE 10CM X 76CM 1 EN FR PRE-CUT LPPR	71419-17
71419-00018-01	DYNACAST PRELUDE 12.5CM X 76CM 1 EN FR PRE-CUT LPPR	71419-18
71420-00000-03	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
71421-00000-03	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
72869-00000-03	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
73418-00000-03	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