

### ECS GmbH - European Certification Service Augenschutz und Persönliche Schutzausrüstung Laserschutz und Optische Messtechnik

# **Test Report**

Nr. 1025-ECS-15

Contact person: Dr. Bernhard Schmitz Phone: +49 (0)7361 9757396

Fax: +49 (0)7361 5562434

E-mail: bernhard.schmitz@ecs-eyesafe.de

Web: www.ecs-eyesafe.de

Test lab accredited by DAkkS D-PL-19590-02-00

ZLS-NB-0156

Notified by the Central

Authority of the Federal States for Safety Technologies (ZLS)

Customer

Small Beginnings, Inc. 17229 Lemon St. Ste. B2 HESPERIA CALIFORNIA 92345 USA Manufacturer

Test report contains

Main part, 1 measurement report

Number of pages in this test report

7

Product

Optically opaque eye-protectors intended for phototherapy applications on newborn children

Arrival of samples

Feb 12, 2014

Period of testing

Feb 12 - 17, 2014

Test specifications (Standards)

DIN EN 166: 2001

#### Remarks

The results described in this test report refer to the mentioned test samples, exclusively. A copy of the test report, complete or in extracts, is not allowed without any written permission of the ECS GmbH Aalen.

Aalen, 18 Feb 2015

Dr. Bernhard Schmitz

ECS manager



### Test objects, tests and results

Based on the tables as written in the standards DIN EN 166 the main part assigns the test samples to the named tests. The test results are documented according to the named standards.

### Signs and symbols

The requirements are described in DIN EN 166

- + meet the requirements
- do not meet the requirements
- / not tested
- n.a. not applicable
- G borderline case
- Ab interruption of the testing sequence
- BO Base out
- BI Base in

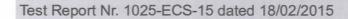
Whenever the dioptric power of the surface is stated, this value was calculated using the formula F=0,523/r, where "r" is the radius of the curved surface.

The relative measurement uncertainties of the applied optical metrological instruments correspond to the required one in DIN EN 167.

Unless stated otherwise, the measurements were carried out in the main viewing point of the specimens and, in the case of lenses with corrective power, at the applicable reference point.

#### Test results

The annexes document the test results of each individual measurement. All results printed in bold and italic type document that the test sample did actually not meet the requirements which are demanded in the specified standards.



### Samples and summary of the test results

Туре:	SMALL BEGINN Bili-Bonnet® Pho 01A Preemie 01B Newborn 01C Ultra-Preen	oto-Therapy Ma		otectors	
Test report:	10251-ECS-15				
Number of del Number of tes	ivered samples: t samples:	30 12			
Test sequence	Require	ement		Tests	Samples
			accordin	ng to	15025-1 to -12
		EN	Clause E	N Clause	

quence	Requirement		Tests	Samples		
		ding to		15025-1 to -12		
		EN	Clause	EN	Clause	
1	Marking	166	9.4			n.a.
2	Information delivered by the manufacturer / applicant	166	10			n.a.
3	Quality of surface and material	166	7.1.3	167	5	+
4	Luminous transmittance rel. NA / D65	166	7.1.2	167	6	+
5	Resistance to ageing - temperature	166	7.1.5	168	5	+
6	Resistance to ageing - UV-irradiation	166	7.1.5	168	6	+
7	Resistance to ignition	166	7.1.7	168	7	+

The SMALL BEGINNINGS eye protectors for phototherapy for newborns are Assessment: optically opaque in the UV, VIS and NIR spectral ranges. The EN 166 has been partially applied for testing.

The SMALL BEGINNINGS eye protectors for phototherapy for newborns satisfy the essential requirements of the Directive for Personal Protective Equipment 89/686/EEC.

Marking: SMALL BEG CE

Aalen, 18 Feb 2015

Dr. Bernhard Schmitz **ECS-Certification** 



Test Report	1025-ECS-15	from 18/02/2015
-------------	-------------	-----------------

Measurement Report 1: Page 1 of 4

Test mark:	10251-ECS-15	
Type:	Phototherapy Eye Protector	

# Measurement Report 1

# Description of the type

Design:	Eye protector for phototherapy for newborns, fabric white, black foam, with Velcro and head band					
	Middle thickness of the lenses (interlayer) / mm: 01A Preemie: $\sim 0.9 \pm 0.05$ 01B Newborn: $\sim 0.9 \pm 0.05$ 01C Ultra-Preemie: $\sim 0.8 \pm 0.05$					
Material:	fabric outer: white fabric inner: black foam black interlayer					
Information from the producer:	User information in each packaging					
01A Preemie LOT FB0727201201A	For Infants approximately 29 through 36 weeks gestation"  **But Sevent seals and bearen are linerabrogashly with etherson class for the everying head shapes of seals and bearen strength					
01B Newborn LOT FB0727201201B	For Infants approximately 37 weeks gestation or above  **matical content and binarch or winderchapaths with different stars to the two-professor of according to the determined by a healthcarp professor of according to the determined by a healthcarp professor of according to the determined by the healthcarp professor of according to the determined by the healthcarp professor of according to the determined by the healthcarp professor of according to the determined by the healthcarp professor of according to the determined by the healthcarp professor of according to the determined by the healthcarp professor of according to the determined by the healthcarp professor of according to the determined by the healthcarp professor of the neck to the foreshead.  5. Make sure gazze netting is farmed out from the naps of the neck to the foreshead.  6. Once you are happy with the netting, resistant the tests to pull up or down as needed.  *For visual instructions go to our web sital products  **Continued observation of the left and its exposure to the naps of the neck to the foreshead.  6. The start of the name of the neck to the foreshead.  6. The start of the name					
01C Ultra-Preemie LOT 19201C-03, 0119201C-01	Patent & SELONS  For Infants approximately 28 weeks gestation or below*  *Ball-Beament masks and bennets are inferthempedies with different also: to fit the varying head shapes of revelues infants. Proper life of mark and bennets with different also: to fit the varying head shapes of revelues infants. Proper life of mark and bennet about he determined by a beathvair professional.  Instructions::(c., 0)  1. Remove from package and give stretch gauze a tug from each Veloro end.  2. Place you'r fist involve gauze and stretch out to create a bonnet.  3. Spread bonnet over back of head, attach tabs to each side of mask to fit snug not tight.  4. Ensure mask is covering both eyes and nares are unobstructed.  5. Make sure gauze netting is famned out from the nape of the neck to the forehead.  6. Once you are happy with the netting, reattach the tabs to pull up or down as needed.  *For visual instructions go to our web afte/products.  GYY: EA  Warning:  Product should be applied by a trained medical professional. Signage of the mask could result in exposure to the light and/or possible nareal debirturction.  Continued observation of the infant is necessary.					



Test I	Report	1025-	ECS-15	from	18/02/2015
--------	--------	-------	--------	------	------------

Measurement Report 1: Page 2 of 4

Test mark:	10251-ECS-15	
Type:	Phototherapy Eye Protector	

# Samples assigned to numbers:

Sample number	Description	Dimensions
	01A Preemie LOT FB0727201201A	170 x 48 mm²
15025-1, -4, -7, -10		
	01B Newborn LOT FB0727201201B	195 x 52 mm²
15025-2, -5, -8, -11		
	01C Ultra-Preemie LOT 19201C-03, 0119201C-01	123 x 30 mm²
15025-3, -6, -9, -12		



Test Report 1025-ECS	3-15 from	18/02/2015
----------------------	-----------	------------

Measurement Report 1: Page 3 of 4

Test mark:	10251-ECS-15	
Type:	Phototherapy Eye Protector	

### Quality of material and surface, transmittance

1		15025						
test ↓ sample →		-1	-2	-3	-4	-5	-6	
quality of material and surface		+	+	+	+	+	+	
luminous transmittance rel NA τ	%	4.3*10 <sup>-6</sup>	4.3*10 <sup>-6</sup>	7.1*10 <sup>-5</sup>	1.9*10 <sup>-6</sup>	2.6*10 <sup>-6</sup>	2.3*10 <sup>-5</sup>	
luminous transmittance rel D65 τ	%	4.1*10 <sup>-6</sup>	4.0*10 <sup>-6</sup>	6.9*10 <sup>-5</sup>	1.7*10 <sup>-6</sup>	2.4*10 <sup>-6</sup>	2.3*10 <sup>-5</sup>	

**Remark:** The eye protectors for phototherapy for newborns are optically opaque in the UV, VIS and NIR spectral ranges.

## Quality of material and surface after test to thermal ageing

test ↓ sample →	15025				
	-1	-2	-3		
quality of material and surface	No visible surface modification after thermal ageing,				

### Quality of material and surface after test to UV ageing

	15025			
test ↓ sample →	-4	-5	-6	
quality of material and surface	No visible depletion, no visible coloring or darkening after UV ageing,			



Test Report 10	25-ECS-15 from	18/02/2015
----------------	----------------	------------

Measurement Report 1: Page 4 of 4

Test mark:	10251-ECS-15	
Type:	Phototherapy Eye Protector	

## Resistance to ignition

test ↓	sample →	15025					
		-7	-8	-9	-10	-11	-12
flammability		temperature > 650 °C strong smoke, no ignition, no further glowing					

Aalen, 18 Feb. 15

MSc. Angelica Soto Duran ECS Test Engineer