NEOTECH Products LLC

Declaration of Conformity Index

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Tel (661) 775-7466 **Fax** (661) 775-7464
neotechproducts.com

Declaration of Conformity Chinstrap

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

MANUFACTURER		
Name of Company	**Address**	**SRN**
Neotech Products LLC	28430 Witherspoon Pkwy Valencia CA 91355 USA	US-MF-000001895

AUTHORIZED REPRESENTATIVE			
Name of Company	**Address**	**SRN**	**Telephone/fax/email**
Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	NL-AR-000000116	+31.70.345.8570 - phone EmergoEurope@ul.com

PRODUCT IDENTIFICATION		
Product Name	**Product Code / Catalog Number**	**Basic UDI-DI**
Chinstrap	N784, N785, N786, N787, N788, N789, N790	081259401N78400P3
Intended Purpose	**Photo**	
The Neotech ChinStrap is intended to help keep a patient's mouth closed during respiratory therapy. It is intended for use on pediatric (neonates, infants and children) patients.		

RISK CLASS FOR MEDICAL DEVICES	
Device Classification	**Common Specifications**
Class _I_ Rule _1__	Non-Invasive device. Only contacts with intact skin. Other rules are not applicable.

Neotech Products LLC declares that the above-mentioned products meet the provision of the following EU legislation:

- MDR (EU) 2017/745

COMPANY REPRESENTATIVE:

Leo Arya

Quality Assurance & Regulatory Affairs Manager

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Leo Arya
Signer Name: Leo Arya
Signing Reason: I approve this document
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Declaration of Conformity EZCare Softouch

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

MANUFACTURER		
Name of Company	**Address**	**SRN**
Neotech Products LLC	28430 Witherspoon Pkwy Valencia CA 91355 USA	US-MF-000001895

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Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	NL-AR-000000116	+31.70.345.8570 - phone EmergoEurope@ul.com

PRODUCT IDENTIFICATION		
Product Name	**Product Code / Catalog Number**	**Basic UDI-DI**
EZCare Softouch	N9105, N9106, N9107, N9108, N9109, N9110, N9111, N925, N926, N926BK	081259401N91050N3

Intended Purpose	**Photo**
The EZCare Softouch is intended to secure a patient's tracheostomy tube. It is intended for use on pediatric (neonates, infants and children) patients.	

RISK CLASS FOR MEDICAL DEVICES	
Device Classification	**Common Specifications**
Class _I_ Rule _1__	Non-Invasive device. Only contacts with intact skin. Other rules are not applicable.

Neotech Products LLC declares that the above-mentioned products meet the provision of the following EU legislation:

- MDR (EU) 2017/745

COMPANY REPRESENTATIVE:

Leo Arya

Quality Assurance & Regulatory Affairs Manager

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Declaration of Conformity EZ-Hold

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Neotech Products LLC	28430 Witherspoon Pkwy Valencia CA 91355 USA	US-MF-000001895

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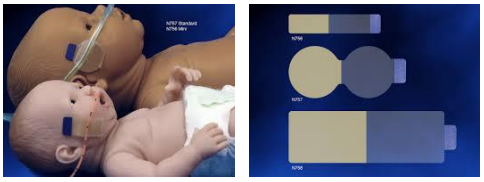
Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	NL-AR-000000116	+31.70.345.8570 - phone EmergoEurope@ul.com

PRODUCT IDENTIFICATION		
Product Name	**Product Code / Catalog Number**	**Basic UDI-DI**
EZ-Hold	N756, N757, N758	081259401N75600NQ
Intended Purpose	**Photo**	
The EZ-Hold is intended to anchor and support breathing tubes.		

RISK CLASS FOR MEDICAL DEVICES	
Device Classification	**Common Specifications**
Class _I_ Rule _1__	Non-Invasive device. Only contacts with intact skin. Other rules are not applicable.

Neotech Products LLC declares that the above-mentioned products meet the provision of the following EU legislation:

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Quality Assurance & Regulatory Affairs Manager

Declaration of Conformity Hold-A-Line

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MANUFACTURER		
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Neotech Products LLC	28430 Witherspoon Pkwy Valencia CA 91355 USA	US-MF-000001895

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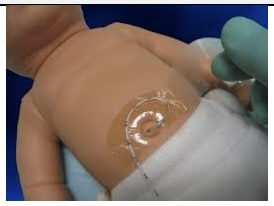
Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	NL-AR-000000116	+31.70.345.8570 - phone EmergoEurope@ul.com

PRODUCT IDENTIFICATION		
Product Name	**Product Code / Catalog Number**	**Basic UDI-DI**
Hold-A-Line	N705	081259401N70500MG
Intended Purpose	**Photo**	
The Hold-A-Line is intended to anchor and support umbilical catheters and tubing. It is intended for use on pediatric (neonates, infants and children) patients.		

RISK CLASS FOR MEDICAL DEVICES	
Device Classification	**Common Specifications**
Class _I_ Rule _1__	Non-Invasive device. Only contacts with intact skin. Other rules are not applicable.

Neotech Products LLC declares that the above-mentioned products meet the provision of the following EU legislation:

- MDR (EU) 2017/745

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Quality Assurance & Regulatory Affairs Manager

Declaration of Conformity Little Sucker

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PRODUCT IDENTIFICATION		
Product Name	**Product Code / Catalog Number**	**Basic UDI-DI**
Little Sucker Family	N204, N204C, N204TP, N205, N205C, N205TP, N215, N224, N224TP, N225, N225TP, N206, N207, N208	081259401N20400KL
Intended Purpose		**Photo**
The Little Sucker/ NeoSucker are indicated to be used as a tip for suction tubing to aspirate fluids from the mouth and nares. The Little Sucker Cover is indicated for use to protect the Little Sucker Device. The Suction Caddy is intended to hold and store a suction device.		

RISK CLASS FOR MEDICAL DEVICES	
Device Classification	**Common Specifications**
Class _I_ Rule _5__	Non-Surgically minimally Invasive (if any) device with respect to body orifices intended for transient Use.

Neotech Products LLC declares that the above-mentioned products meet the provision of the following EU legislation:

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Leo Arya

Quality Assurance & Regulatory Affairs Manager

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Declaration of Conformity Meconium Aspirator

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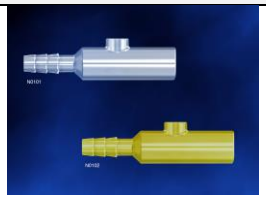
Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	NL-AR-000000116	+31.70.345.8570 - phone EmergoEurope@ul.com

PRODUCT IDENTIFICATION		
Product Name	**Product Code / Catalog Number**	**Basic UDI-DI**
Meconium Aspirator	N0101, N0102	081259401N01010JL
Intended Purpose	**Photo**	
The Neotech Meconium Aspirator is intended for use as a suction device to aspirate meconium from a newborn's upper airway.		

RISK CLASS FOR MEDICAL DEVICES	
Device Classification	**Common Specifications**
Class _I_ Rule _1__	Non-Invasive device. No skin contact. Other rules are not applicable.

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Declaration of Conformity NeoBar

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MANUFACTURER		
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Neotech Products LLC	28430 Witherspoon Pkwy Valencia CA 91355 USA	US-MF-000001895

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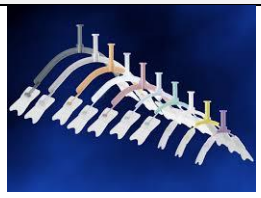
Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	NL-AR-000000116	+31.70.345.8570 - phone EmergoEurope@ul.com

PRODUCT IDENTIFICATION		
Product Name	**Product Code / Catalog Number**	**Basic UDI-DI**
NeoBar	N709, N710, N711, N712, N713, N714, N715H, N715F, N716H, N716F, N718, N719	081259401N70900N4
Intended Purpose	**Photo**	
The NeoBar is intended to secure an endotracheal tube. It is intended for use on pediatric (neonates, infants and children) patients.	 	

RISK CLASS FOR MEDICAL DEVICES	
Device Classification	**Common Specifications**
Class _I_ Rule _1__	Non-Invasive device. Only contacts with intact skin. Other rules are not applicable.

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Leo Arya

Quality Assurance & Regulatory Affairs Manager

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Declaration of Conformity NeoBond

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MANUFACTURER		
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Neotech Products LLC	28430 Witherspoon Pkwy Valencia CA 91355 USA	US-MF-000001895

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Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	NL-AR-000000116	+31.70.345.8570 - phone EmergoEurope@ul.com

PRODUCT IDENTIFICATION		
Product Name	**Product Code / Catalog Number**	**Basic UDI-DI**
NeoBond	N741, N742	081259401N74100MQ
Intended Purpose	**Photo**	
NeoBond Hydrocolloid Adhesive is intended for general use as a medical adhesive.	 	

RISK CLASS FOR MEDICAL DEVICES	
Device Classification	**Common Specifications**
Class _I_ Rule _1__	Non-Invasive device. Only contacts with intact skin. Other rules are not applicable.

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COMPANY REPRESENTATIVE:

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Leo Arya

Quality Assurance & Regulatory Affairs Manager

Declaration of Conformity NeoBridge

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MANUFACTURER		
Name of Company	**Address**	**SRN**
Neotech Products LLC	28430 Witherspoon Pkwy Valencia CA 91355 USA	US-MF-000001895

AUTHORIZED REPRESENTATIVE			
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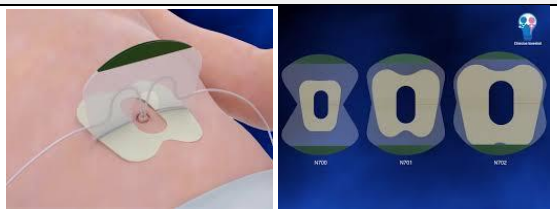
Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	NL-AR-000000116	+31.70.345.8570 - phone EmergoEurope@ul.com

PRODUCT IDENTIFICATION		
Product Name	**Product Code / Catalog Number**	**Basic UDI-DI**
NeoBridge	Catalog Numbers N700, N701, N702	081259401N70000LP
Intended Purpose	**Photo**	
The NeoBridge is intended to anchor and support umbilical catheters. It is intended for use on pediatric (neonates, infants and children) patients.		

RISK CLASS FOR MEDICAL DEVICES	
Device Classification	**Common Specifications**
Class _I_ Rule _I_	Non-Invasive device. Only contacts with intact skin. Other rules are not applicable.

Neotech Products LLC declares that the above-mentioned products meet the provision of the following EU legislation:

- MDR (EU) 2017/745

COMPANY REPRESENTATIVE:

Leo Arya

Quality Assurance & Regulatory Affairs Manager

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Signing Time: 03/05/2021 | 9:38:16 AM PST
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Declaration of Conformity NeoGrip & VersaGrip

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

MANUFACTURER		
Name of Company	**Address**	**SRN**
Neotech Products LLC	28430 Witherspoon Pkwy Valencia CA 91355 USA	US-MF-000001895

AUTHORIZED REPRESENTATIVE			
Name of Company	**Address**	**SRN**	**Telephone/fax/email**
Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	NL-AR-000000116	+31.70.345.8570 - phone EmergoEurope@ul.com

PRODUCT IDENTIFICATION		
Product Name	**Product Code / Catalog Number**	**Basic UDI-DI**
NeoGrip & VersaGrip	N601, N602P, N602B, N602R, N602G, N602Y, N602O, N602V, N602PB, N602A, N603	081259401N60100LH
Intended Purpose	**Photo**	
The NeoGrip/VersaGrip is intended to organize tubes, cables and circuits.		

RISK CLASS FOR MEDICAL DEVICES	
Device Classification	**Common Specifications**
Class _I_ Rule _1__	Non-Invasive device. No Skin Contact. Other rules are not applicable.

Neotech Products LLC declares that the above-mentioned products meet the provision of the following EU legislation:

- MDR (EU) 2017/745

COMPANY REPRESENTATIVE:

Leo Arya

Quality Assurance & Regulatory Affairs Manager

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Declaration of Conformity NeoHeart

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MANUFACTURER		
Name of Company	**Address**	**SRN**
Neotech Products LLC	28430 Witherspoon Pkwy Valencia CA 91355 USA	US-MF-000001895

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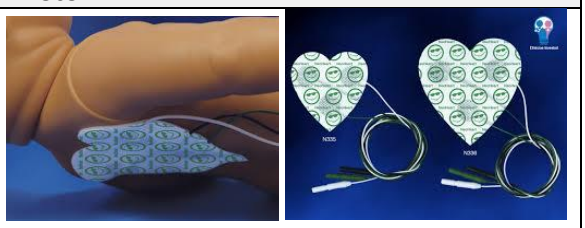
Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	NL-AR-000000116	+31.70.345.8570 - phone EmergoEurope@ul.com

PRODUCT IDENTIFICATION		
Product Name	**Product Code / Catalog Number**	**Basic UDI-DI**
NeoHeart	N335, N336	081259401N33500LR

Intended Purpose	**Photo**
NeoHeart is a set of three attached ECG electrodes used on term neonates, infants, and pediatric patients. An electrocardiograph electrode is the electrical conductor which is applied to the surface of the body to transmit the electrical signal at the body surface to a processor that produces an electrocardiogram or vector cardiogram.	

RISK CLASS FOR MEDICAL DEVICES	
Device Classification	**Common Specifications**
Class _I_ Rule _1_	Non-Invasive device. Only contacts with intact skin. Other rules are not applicable.

Neotech Products LLC declares that the above-mentioned products meet the provision of the following EU legislation:

- MDR (EU) 2017/745

COMPANY REPRESENTATIVE:

Leo Arya

Quality Assurance & Regulatory Affairs Manager

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Leo Arya
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Declaration of Conformity NeoHug

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MANUFACTURER		
Name of Company	**Address**	**SRN**
Neotech Products LLC	28430 Witherspoon Pkwy Valencia CA 91355 USA	US-MF-000001895

AUTHORIZED REPRESENTATIVE			
Name of Company	**Address**	**SRN**	**Telephone/fax/email**
Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	NL-AR-000000116	+31.70.345.8570 - phone EmergoEurope@ul.com

PRODUCT IDENTIFICATION		
Product Name	**Product Code / Catalog Number**	**Basic UDI-DI**
NeoHug	N680BL-S, N680GR-S, N680BO-S, N680BP-S, N680VL-S, N680A-S, N680BL-C, N680GR-C, N680BO-C, N680BP-C, N680VL-C, N680A-C, N681A-S, N681A-C	081259401N68000N4
Intended Purpose	**Photo**	
NeoHug is intended to support, organize or hold Non-operating medical devices. No specific patient/user population is applicable.		

RISK CLASS FOR MEDICAL DEVICES	
Device Classification	**Common Specifications**
Class _I_ Rule _1__	Non-Invasive device. Does not contact patient. Other rules are not applicable.

Neotech Products LLC declares that the above-mentioned products meet the provision of the following EU legislation:

- MDR (EU) 2017/745

COMPANY REPRESENTATIVE:

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Quality Assurance & Regulatory Affairs Manager

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Declaration of Conformity NeoLead

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MANUFACTURER		
Name of Company	**Address**	**SRN**
Neotech Products LLC	28430 Witherspoon Pkwy Valencia CA 91355 USA	US-MF-000001895

AUTHORIZED REPRESENTATIVE			
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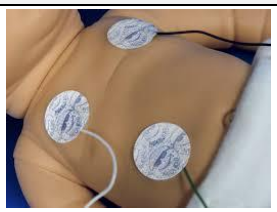
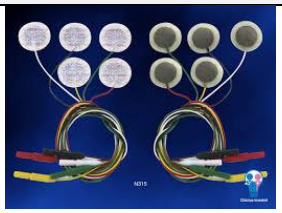
Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	NL-AR-000000116	+31.70.345.8570 - phone EmergoEurope@ul.com

PRODUCT IDENTIFICATION		
Product Name	**Product Code / Catalog Number**	**Basic UDI-DI**
NeoLead	Catalog Numbers N300, N301, N305, N306, , N315	081259401N30000KB
Intended Purpose	**Photo**	
NeoLead is a set of three/five ECG electrodes used on term neonates, infants, and pediatric patients. An electrocardiograph electrode is the electrical conductor which is applied to the surface of the body to transmit the electrical signal at the body surface to a processor that produces an electrocardiogram or vectorcardiogram.		

RISK CLASS FOR MEDICAL DEVICES	
Device Classification	**Common Specifications**
Class _I_ Rule _1_	Non-Invasive device. Only contacts with intact skin. Other rules are not applicable.

Neotech Products LLC declares that the above-mentioned products meet the provision of the following EU legislation:

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Declaration of Conformity Neopulse

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MANUFACTURER		
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Neotech Products LLC	28430 Witherspoon Pkwy Valencia CA 91355 USA	US-MF-000001895

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Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	NL-AR-000000116	+31.70.345.8570 - phone EmergoEurope@ul.com

PRODUCT IDENTIFICATION		
Product Name	**Product Code / Catalog Number**	**Basic UDI-DI**
Neopulse	N781, N782, N783	081259401N78100NL
Intended Purpose	**Photo**	
The NeoPulse is intended to hold a pulse oximeter sensor in place. It is intended for use on pediatric (neonates, infants and children) patients.	 	

RISK CLASS FOR MEDICAL DEVICES	
Device Classification	**Common Specifications**
Class _I_ Rule _I	Non-Invasive device. Only contacts with intact skin. Other rules are not applicable.

Neotech Products LLC declares that the above-mentioned products meet the provision of the following EU legislation:

- MDR (EU) 2017/745

COMPANY REPRESENTATIVE:

Leo Arya

Quality Assurance & Regulatory Affairs Manager

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Declaration of Conformity NeoSeal

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MANUFACTURER		
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Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	NL-AR-000000116	+31.70.345.8570 - phone EmergoEurope@ul.com

PRODUCT IDENTIFICATION		
Product Name	**Product Code / Catalog Number**	**Basic UDI-DI**
NeoSeal	N420, N421, N422	081259401N42000L4
Intended Purpose	**Photo**	
The NeoSeal is intended to create a seal around the nares and protect the skin of the septum and nares. It is intended for use on pediatric (neonates, infants and children) patients.		

RISK CLASS FOR MEDICAL DEVICES	
Device Classification	**Common Specifications**
Class _I_ Rule _1_	Non-Invasive device. Only contacts with intact skin. Other rules are not applicable.

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Leo Arya

Quality Assurance & Regulatory Affairs Manager

Declaration of Conformity NeoShades

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MANUFACTURER		
Name of Company	**Address**	**SRN**
Neotech Products LLC	28430 Witherspoon Pkwy Valencia CA 91355 USA	US-MF-000001895

AUTHORIZED REPRESENTATIVE			
Name of Company	**Address**	**SRN**	**Telephone/fax/email**
Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	NL-AR-000000116	+31.70.345.8570 - phone EmergoEurope@ul.com

PRODUCT IDENTIFICATION		
Product Name	**Product Code / Catalog Number**	**Basic UDI-DI**
NeoShades	N720, N721, N722, N724, N725, N726, N727, N728, N729	081259401N72000M5

Intended Purpose	**Photo**
The NeoShades are indicated for use as eye protection during phototherapy sessions. They are intended for use on pediatric (neonates, infants and children) patients.	

RISK CLASS FOR MEDICAL DEVICES	
Device Classification	**Common Specifications**
Class _I_ Rule _1__ + Category II PPE Directive	Non-Invasive device. Only contacts with intact skin. Other rules are not applicable.

NOTIFIED BODY			
Name of Company	**ID Number**	**Conformity Assessment Procedure**	**Certificate Reference(s)**
BSI	Notified Body 2797	Neotech Products LLC declares that the above mentioned products meet the provision of the Annex II of legislation (EU) 2016/425 of 9 March 2016 on the personal protective equipment	CE 693481

Neotech Products LLC declares that the above-mentioned products meet the provision of the following EU legislation:

- MDR (EU) 2017/745
- PPE (EU) 2016/425

COMPANY REPRESENTATIVE:

Leo Arya

Quality Assurance & Regulatory Affairs Manager

DocuSigned by:
Leo Arya
Signer Name: Leo Arya
Signing Reason: I approve this document
Signing Time: 03/05/2021 | 9:39:31 AM PST
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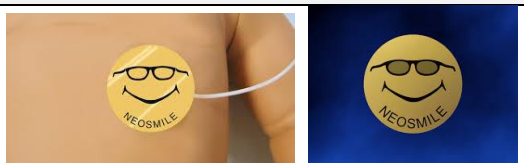
Declaration of Conformity NeoSmile

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

MANUFACTURER		
Name of Company	**Address**	**SRN**
Neotech Products LLC	28430 Witherspoon Pkwy Valencia CA 91355 USA	US-MF-000001895

AUTHORIZED REPRESENTATIVE			
Name of Company	**Address**	**SRN**	**Telephone/fax/email**
Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	NL-AR-000000116	+31.70.345.8570 - phone EmergoEurope@ul.com

PRODUCT IDENTIFICATION		
Product Name	**Product Code / Catalog Number**	**Basic UDI-DI**
NeoSmile	N731, N7320	081259401N73100MH
Intended Purpose	**Photo**	
NeoSmile is intended to cover and secure a temperature probe.		

RISK CLASS FOR MEDICAL DEVICES	
Device Classification	**Common Specifications**
Class _I_ Rule _1_	Non-Invasive device. Only contacts with intact skin. Other rules are not applicable.

Neotech Products LLC declares that the above-mentioned products meet the provision of the following EU legislation:

- MDR (EU) 2017/745

COMPANY REPRESENTATIVE:

Leo Arya

Quality Assurance & Regulatory Affairs Manager

DocuSigned by:
Leo Arya
Signer Name: Leo Arya
Signing Reason: I approve this document
Signing Time: 03/05/2021 | 9:39:45 AM PST
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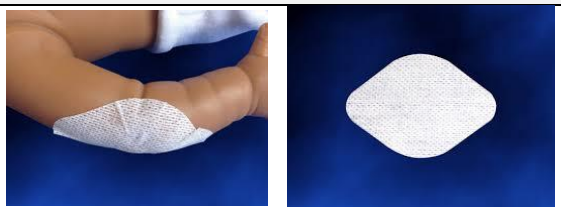
Declaration of Conformity SoftSil

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

MANUFACTURER		
Name of Company	**Address**	**SRN**
Neotech Products LLC	28430 Witherspoon Pkwy Valencia CA 91355 USA	US-MF-000001895

AUTHORIZED REPRESENTATIVE			
Name of Company	**Address**	**SRN**	**Telephone/fax/email**
Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	NL-AR-000000116	+31.70.345.8570 - phone EmergoEurope@ul.com

PRODUCT IDENTIFICATION		
Product Name	**Product Code / Catalog Number**	**Basic UDI-DI**
SoftSil	N745	081259401N74500NC
Intended Purpose	**Photo**	
SoftSil Silicon Adhesive Patch intended for general use as a medical adhesive.		

RISK CLASS FOR MEDICAL DEVICES	
Device Classification	**Common Specifications**
Class _I_ Rule _1_	Non-Invasive device. Only contacts with intact skin. Other rules are not applicable.

Neotech Products LLC declares that the above-mentioned products meet the provision of the following EU legislation:

- MDR (EU) 2017/745

COMPANY REPRESENTATIVE:

Leo Arya

Quality Assurance & Regulatory Affairs Manager

DocuSigned by:
Leo Arya
Signer Name: Leo Arya
Signing Reason: I approve this document
Signing Time: 03/05/2021 | 9:39:57 AM PST
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Declaration of Conformity Suction Caddy

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

MANUFACTURER		
Name of Company	**Address**	**SRN**
Neotech Products LLC	28430 Witherspoon Pkwy Valencia CA 91355 USA	US-MF-000001895

AUTHORIZED REPRESENTATIVE			
Name of Company	**Address**	**SRN**	**Telephone/fax/email**
Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	NL-AR-000000116	+31.70.345.8570 - phone EmergoEurope@ul.com

PRODUCT IDENTIFICATION		
Product Name	**Product Code / Catalog Number**	**Basic UDI-DI**
Suction Caddy	N245	081259401N24500LM

Intended Purpose	**Photo**
The Suction Caddy is intended to hold and store a Suction tubing and tip.	

RISK CLASS FOR MEDICAL DEVICES	
Device Classification	**Common Specifications**
Class _I_ Rule _1__	Non-Invasive device. Does not contact patient. Other rules are not applicable.

Neotech Products LLC declares that the above-mentioned products meet the provision of the following EU legislation:

- MDR (EU) 2017/745

COMPANY REPRESENTATIVE:

DocuSigned by:
Leo Arya
Signer Name: Leo Arya
Signing Reason: I approve this document
Signing Time: 03/05/2021 | 9:40:10 AM PST
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Leo Arya

Quality Assurance & Regulatory Affairs Manager

Declaration of Conformity

Manufacturer:	**Neotech Products LLC** 28430 Witherspoon Parkway Valencia, CA 91355
Certificate Number	**CE 678314**
Authorized EC Representative:	Emergo Group Prinsessegracht 20 2514 AP The Hague The Netherlands
Notified Body:	BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands **Reference number for Notified Body 2797**
Manufacturing Facility:	Manufacturing Site: same as above

Product Model No.

Model No.	Patient Class	Model Name/Size
N4900	Neonatal	Micro Preemie
N4901	Neonatal	Preemie
N4902	Neonatal	Newborn
N4903	Neonatal	Infant
N4904	Pediatric	Small
N4905	Pediatric	Medium
N4906	Pediatric	Large

Product Model Description:	RAM Cannula
Classification:	Class IIa, Rule 5
Conformity Assessment Route:	Annex VI of the Directive 93/42/EEC as amended by 2007/47/EC

I, the undersigned, hereby declare and authorize to certify that the Medical Device(s) specified above meets the provisions of Directive 93/42/EEC (MDD) which apply to them, as transposed into the national laws of the EU member states. In addition, we declare that our product meets the provisions as laid out under Annex I of the Essential Requirements as required under the same directive.

This declaration is based on the MDD, Annex VI. EC Certificate #678314 was issued by BSI, notified body(NB# 0086) on 2018-05-09 from UK headquarter and then it was reissued with BSI Headquarter in Netherlands (NB# 2797) on 2019-02-04 and the expiration date of 2023-05-08. All the products that carry 0086 numer on the box, can still be used up to their expiration date listed on the package/container.

Name *Leo Arya* title *QA/RA Manager*

Place: *Valencia, CA, USA* Date: *2019.04.30*

Signature: