

DECLARATION OF CONFORMITY

Manufacturer: TIMPEL S.A.
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Product: Electrode Belt			
Trade Name	Product Code	Basic UDI-DI	Intended Use
ENLIGHT Belt	Size P0 – Right (ACE-0001W) Size P0 – Left (ACE-0001X) Size P1 – Right (ACE-0001Y) Size P1 – Left (ACE-0001Z) Size P2 – Right (ACE-00010) Size P2 – Left (ACE-00011) Size 5S – Right (ACE-0001R) Size 5S – Left (ACE-0001T) Size 4S – Right (ACE-0001U) Size 4S – Left (ACE-0001V) Size XXS – Right (ACE-0001C) Size XXS – Left (ACE-0001D) Size XS – Right (ACE-0001E) Size XS – Left (ACE-0001F) Size S – Right (ACE-0001G) Size S – Left (ACE-0001H) Size M – Right (ACE-0001J) Size M – Left (ACE-0001L) Size L – Right (ACE-0001M) Size L – Left (ACE-0001N) Size XL – Right (ACE-0001P) Size XL – Left (ACE-0001Q)	7898959841REUSBELTJF	The electrode belt is used to apply and acquire patient's electrical impedance signals. Biocompatible, non-invasive and latex-free accessory in different sizes for adult, pediatric and neonatal patients, designed for exclusive use with ENLIGHT. Non-sterile and not to be sterilized. The reusable version is used with Addere. The disposable version does not require Addere.
Risk Class:	The ENLIGHT Belt is classified as class 1 according to rule 1 as per annex VIII, chapter III of REGULATION (EU) 2017/745		
Accessory: Addere			
Trade Name	Product Code	Basic UDI-DI	Intended Use
ENLIGHT Addere	Size P0 (ACE-0000P) Size P1 (ACE-0000Q) Size P2 (ACE-0000R) Size 5S (ACE-0000D) Size 4S (ACE-0000E)	7898959841ADDERE3Y	Addere is a disposable accessory that envelopes the electrode belt and works as the interface between the electrode belt and the patient's body. Biocompatible, non-

	Size XXS (AD-03005) Size XS (AD-03006) Size S (AD-03007) Size M (AD-03008) Size L (AD-03009) Size XL (AD-0300A)		invasive and latex-free accessory in different sizes for adult and pediatric patients, designed for exclusive use with ENLIGHT Electrode Belts. Non-sterile and not to be sterilized.
Risk Class:	The ENLIGHT Addere is classified as class 1 according to rule 1 as per annex VIII, chapter III of REGULATION (EU) 2017/745		
Accessory: Shaper			
Trade Name	Product Code	Basic UDI-DI	Intended Use
ENLIGHT Shaper	AD-05001 AD-05002	7898959841SHAPERDB	The shaper is a disposable accessory to assist the Electrode Belt to better fit the contour of the patient's chest, if needed. Available in two sizes, biocompatible, non-invasive, non-sterile and not to be sterilized.
Risk Class:	The ENLIGHT Shaper is classified as class 1 according to rule 1 as per annex VIII, chapter III of REGULATION (EU) 2017/745		
Product: Electrode Disposable Belt			
Trade Name	Product Code	Basic UDI-DI	Intended Use
ENLIGHT Disposable Belt	Size N0 (ACE-00002) Size N1 (ACE-00003) Size N2 (ACE-00004) Size N3 (ACE-00005) Size N4 (ACE-00006) Size N5 (ACE-00007)	7898959841DISPBELTAE	The electrode belt is used to apply and acquire patient's electrical impedance signals. Biocompatible, non-invasive and latex-free accessory in different sizes for adult, pediatric and neonatal patients, designed for exclusive use with ENLIGHT. Non-sterile and not to be sterilized. The reusable version is used with Addere. The disposable version does not require Addere.
Risk Class:	The ENLIGHT Disposable Belt is classified as class 1 according to rule 1 as per annex VIII, chapter III of REGULATION (EU) 2017/745		
Accessory: Adapter Cable			
Trade Name	Product Code	Basic UDI-DI	Intended Use
ENLIGHT Adapter Cable	Right (ACE-00012) Left (ACE-00013)	7898959841ADAPTCABLEDS	The adapter cable is used to connect the disposable electrode belt to ENLIGHT. The cable has been developed for exclusive use with ENLIGHT. Reusable, non-sterile and not to be sterilized.

Risk Class:	The ENLIGHT Adapter Cable is classified as class 1 according to rule 1 as per annex VIII, chapter III of REGULATION (EU) 2017/745		
Product: Reference Cable			
Trade Name	Product Code	Basic UDI-DI	Intended Use
ENLIGHT Reference Cable	DX-0TC03	7898959841REFCABLE58	The reference cable is connected to a common ECG-like electrode applied to the patient to acquire reference signal of electric impedance data. The accessory has been developed for exclusive use with ENLIGHT. Non-sterile and not to be sterilized.
Risk Class:	The ENLIGHT Reference Cable is classified as class 1 according to rule 1 as per annex VIII, chapter III of REGULATION (EU) 2017/745		

This declaration of conformity is issued under the sole responsibility of TIMPEL S.A.

We, the manufacturer, declare under our own responsibility that the listed products in this declaration are in conformity with REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 and DIRECTIVE 2011/65/EU OF THE EUROPEAN PARLIAMENT AND OF THE CONCIL of 8 June 2011.

We, the manufacturer, declare under our own responsibility that the listed products in this declaration are in conformity with the directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

São Paulo, March 02nd 2021



Rafael Holz hacker
President






DC.ACE.02B_EN - Declaration of Conformity - ENLIGHT Accessories

Relatório de auditoria final

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