

		BL LIFESCIENCES PVT. LTD. 28-D, Sector-31, Ecotech-I, Greater Noida, Gautam Buddha Nagar, Uttar Pradesh-(India)	
		DECLARATION OF CONFORMITY	
Document Ref. No.	INSP/F21	Effective Date	06-08-2020
Revision	01	Page No.	1 of 1

According to annex –II excluding section 4 of the MDD 93/42/EEC & by amended directive 2007/47/EC concerning medical devices we: **BL Lifesciences Pvt. Ltd., 28-D, Sector-31, Ecotech-I, Greater Noida Gautam Budh Nagar, 201306, U.P., India.**

Declare under our sole responsibility that the product:

Brand	PerfX
Name of product Category	Heart Lung Pack
Name of product	Heart Lung Pack
Part No	BHL-XXXX
Classification	Ila, as per rule 2 of MDD 93/42/EEC, Annex IX, Meets the provisions of the MDD 93/42EEC & by amended directive 2007/47/EC concerning medical devices which apply to them

Meets the provisions of the MDD 93/42/EEC & by amended directive 2007/47/EC concerning medical devices which apply to them:

We have presented our product as well as our quality management system to the notified body 'DNV₂₄₆₀' for assessment as per the requirements of MDD 93/42/EEC as amended by 2007/47/EC.

Following standards were used to prove the products conformity with the essential requirements of the Directive:

[EN ISO 14971: 2012], [EN ISO 14155 (Part 1&2) : 2011],[EN 62366:2008], [EN ISO 10993 –1:2009 , 10993 –3:2014, 10993 –4:2009, 10993 –5:2009, 10993 –6:2009, 10993 –7:2010, 10993 –9:2009, 10993 –11:2009, 10993 –12:2009, 10993 –13:2010, 10993 –14:2009, 10993 –15:2009, 10993 –16:2010, 10993 –17:2009, 10993 –18:2009], [EN ISO 10993-10:2010],[EN ISO 10993-12:2012], [EN ISO 11607-1 :2009], [EN ISO 11607-2:2006], [EN ISO 13485:2016], [ISO 14644 – 1 : 2015, 14644 – 2 : 2015], [EN ISO 15223:2016], [ISO 11137-1:2006], [ISO 11139:2006], [ISO 11135:2014], [ISO 11138-1:2009, 11138-2:2009, 11138-3:2009], [EN ISO 11140-1 :2009], [EN ISO 11135:2007], [IP -2017].

Signatory established within the EU who has been empowered to enter into commitments on our behalf:



B L Lifesciences Pvt. Ltd.
 28-D, Sector-31, Ecotech-I, Greater Noida,
 Gautam Budh Nagar, 201306, U.P., India

EC|REP

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NOTIFIED BODY:

DNV GL Presafe AS

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NOTIFIED BODY NO: 2460

CE Certificate No: 10532-2017-CE-IND-NA-PS Rev. 2.0

CE Certificate Valid up to: 12th December 2022

Priyanka Sachan

HOD Quality



08/10/2020

Date of Issue