

DECLARATION OF CONFORMITY		
Product Identification		
Trypan Blue Ophthalmic Solution 0.6mg/ml		
Brand: BIO-BLUE	Presentation: 1ml vial	GMDN Code: 45180
Product Description		
Trypan Blue (0.06% w/v) Ophthalmic Solution		
Batch No. XXXXX	Exp. Date YYYY/MM	
Manufacturer:		
Bio-Tech Vision Care Pvt. Ltd.		
Plot no. 555-556-557 Khatraj-Vadsar Road, Opp Subham Tex-o-Pack, Vill. Khatraj, Taluka- Kalol, Dist. Gandhinagar, Gujarat, India		
Authorized Representative		
Biotech Europe Meditech Inc Limited, AF2, IDA Business & Technology Park, Roscommon, Ireland		
Standards Applied		
EN ISO 13485:2016+A11:2021, EN ISO 17665-1:2006, EN 556-1:2001+AC:2006, EN ISO 14971: 2019+A11:2021, ISO 20417:2021, EN ISO 15223-1:2021, ISO 2859-1:1999+Amd1:2011, ISO 10993-1:2018, EN ISO 10993-3:2014, EN ISO 10993-5:2009, ISO 10993-10:2021, EN ISO 10993-11:2018, ISO 10993-12:2021, ISO 10993-18:2020+AMD1:2022, ISO/TS 10993-19:2020, EN ISO 11737-1:2018+A1:2021, EN ISO 11737-2:2020, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN ISO 14155:2020, IEC 62366-1:2015+AMD1:2020, ISO 14698-1:2003, ISO 14698-2:2003+Cor1:2004, ISO 14644-1:2015, ISO 14644-2:2015, ISO 14630:2012		

-) We hereby confirm that the product fulfills the requirements for a CE-mark for Class IIb Medical Device according to Rule 8, Annex IX of Council Directive 93/42/EEC as amended by 2007/47/EC.
-) The product is in conformance with requirements according to the essential safety requirements as per Annex I and Route of conformity assessment as per Annex II excluding section 4 of the Council Directive 93/42/EEC, as amended by 2007/47/EC.
-) The product is manufactured according to Good Manufacturing Practices.

BIOTECH VISION CARE PVT. LTD.

Manufacturing Unit 1:

Plot No. 555-556-557,
Opp. Subham Tex-O-Pack,
Khatraj-Vadsar Road,
P.O.: Khatraj, Taluka, Kalol,
Dist. Gandhinagar,
Gujarat, India
☎ + 91 - 02764-662000

Manufacturing Unit 2:

Plot No. 4,
PHARMEZ, Sarkhej-Bavla N.H.
8A, Village: Matoda,
Taluka: Sanand, Dist.:
Ahmedabad- 382213,
Gujarat, India
☎ + 91 - 02717-681800

Manufacturing Unit 3:

First floor,
Plot no. 555, 556, 557 Khatraj-
Vadsar Road, Opp. Shubham
Tex-O-Pack, Village Khatraj, Taluka
Kalol, Dist. Gandhinagar,
Gujarat, India
☎ + 91 - 02764-662000

CORPORATE OFFICE

Block 1,
Abhishree Corporate Park,
Opp. Swagat Bunglow, BRTS Stop
Bopal - Ambli Road,
Ahmedabad - 380 058
Gujarat, India,
☎ + 91 - 79 - 66823000

-) The manufacturer is responsible for quality control of the product.
-) Notified Body: DNV Product Assurance AS (Id: 2460), Address: Veritasveien 1, 1363 Høvik, Norway.
-) CE certification No. 10000368344-PA-NA-IND Rev. 0.0 Validity date: 27 May 2024.
-) This declaration is on the sole responsibility of the manufacturer.

Signature:

Name

  Suyog Shah

Title : AGM-Quality Assurance

Place & Date : Ahmedabad & April 26th, 2023

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