

DECLARATION OF CONFORMITY		
Product Identification Iris Retractor	SRN Number: IN-MF-00008482 Basic UDI-DI Number: 8905286IRISBC	Brand name: IRIS RETRACTOR GMDN Code: 46698
Product Description and Intended purpose: Iris Retractor The flexible Iris Retractor enables the mechanical dilation of the pupil where dilation cannot be achieved pharmacologically.		
Batch No XXXX	Exp. Date YYYY/MM	
Manufacturer: Bio-Tech Vision Care Pvt. Ltd. Plot No. 555-556-557, Opp. Subham Tex-O-Pack, Khatraj-Vadsar Road, P.O.: 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 11135:2014+A1:2019, EN 556-1:2001+AC:2006, EN ISO 14971: 2019+A11:2021, EN ISO 15223-1:2021, ISO 2859-1:1999+Amd1:2011, ISO 10993-1:2018, EN ISO 10993-5:2009, ISO 10993-7:2008+Amd1:2019, EN ISO 10993-9:2021, ISO 10993-10:2021, EN ISO 10993-12:2021, EN ISO 10993-18:2020, ISO 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, ISO 20417:2021, ISO 14698-1:2003, ISO 14698-2:2003+Cor1:2004, ISO 14644-1:2015, ISO 14644-2:2015, ISO 2247:2000		

-) We hereby confirm that the product fulfills the requirements for a CE-mark for Class IIa Medical Device according to Rule 6, Annex VIII of **REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL.**
-) The product is in conformance with requirements according to the General Safety and performance requirements as per Annex I and Route of conformity assessment as per Annex IX of Regulation (EU) 2017/745 of European Parliament and of Council.
-) The product is manufactured according to Good Manufacturing Practices.
-) The manufacturer is responsible for quality control of the product.

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

-) Notified Body: DNV Product Assurance AS (Id: 2460), Address: Veritasveien 1, 1363 Høvik, Norway.
-) CE certification No. C528629-NoMA-IND Rev. 2.0 Validity date: 12 March 2027.
-) This declaration is on the sole responsibility of the manufacturer.

Signature:




Name : Suyog Shah
Title : AGM-Quality Assurance
Place& Date : Ahmedabad & April 26th, 2023

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 Bungalow, BRTS Stop
Bopal - Ambli Road,
Ahmedabad - 380 058
Gujarat, India,
☎ + 91 - 79 - 66823000