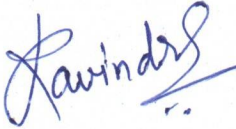


# Contacare Ophthalmics and Diagnostics

Block No. : 310/B&E, Dabhasa, Tal. : Padra, Dist. Vadodara - 391 440. Gujarat, India.  
Phone : +91-7490-002-556 \ 553 \ 557 \ 517, Fax : +91-2662-244241 I www.caregroupiol.com I customercare@caregroupindia.com

## DECLARATION OF CONFORMITY CE 2460

1. **Manufacturer's Name** : Contacare Ophthalmics & Diagnostics  
**Address** : 310/B&E, Dabhasa Village, Padra Taluka, Vadodara District-391440, Gujarat, India
2. **Product Name & Brand Name** : Schirmer Tear Test Strips  
: Tear Strips
3. **Declaration** : We hereby declare on our sole responsibility that the above device is in conformity with the essential requirement of European council Directive of Medical Device 93/42/EEC, as amended by 2007/47/EC of 21<sup>st</sup> march, 2010, and is classified as class IIa device.  
Route of Conformity assessment: Annex II ( Excl-4)
4. **Applicable Standard** : EN ISO 13485:2016  
EN ISO 14971:2012  
EN ISO 10993-1:2009  
EN ISO 11607-1:2009  
EN ISO 11135:2014  
EN 1041:2008
5. **Notified Body** : DNV GL PRESAFE AS  
: Certificates No. **240391-2017-CE-IND-PS Rev 1.0**  
Classification : **Class IIa**  
Validity : **19 April 2023**
6. **European Representative** :  
Name : Mr. Nick Da Costa  
Address : Biovision Limited,  
Wayside, Tring Road Wellhead  
Dunstable, BEDS LU62JU, UK  
Tel No.: 01582 607966 Fax: 01582 661110  
E mail: [biovisionuk@hotmail.com](mailto:biovisionuk@hotmail.com)
7. **Signature** : 
8. **Name & Designation** : Mr. Ravindra Firre , Manager – R.A.
9. **Issue Date & Location** : September 17, 2020 Village Dabhasa, Padra, Vadodara Gujarat, India.

