	<b>STP2-Annex I</b>	<b>REV. 09</b>
	<b>Unique solutions for contact lenses, sterile</b>	<b>Emission date: 03/03/2023</b>

**CERTIFICATE OF CONFORMITY**  
*in accordance with Annex II MDD 93/42/EEC*

**Manufacturer:** SCHALCON S.p.A. - Viale Enrico Ortolani 195, 00125 Rome, Italy

Medical Device Trade Name	Schalcon Technical File Reference	Class (rule)	Product code
Best View ALL-IN-ONE HART, 360 ml	STP2 – Unique solution (var. 1 cod. UV)	IIb (rule 15)	8019894094752


Schalcon S.p.A. declares that the above mentioned medical devices meet the provisions of the following EC Council Directives and Standards:

Council Directive 93/42/CEE of 14 June 1993 and further amendments concerning medical devices, Council Directive 2007/47/EEC of 5 September 2007 and further amendments concerning medical devices, EN ISO 13485:2016, EN ISO 14971:2012, UNI EN CEI ISO 15223-1:2017, EN 556-2:2015, UNI CEI EN 1041:2013, UNI EN ISO 10993-1:2010.

The Technical File containing the relevant documentation is kept by the Manufacturer and is available to the Competent Authorities and the Notified Body.

The CE marking has been granted by the Notified Body:  
**Eurofins Product Testing Italy S.r.l.** (Via Cuorgnè 21 – 10156 Turin - Italy)  
Certificate number: **EPT 0477.MDD.20/4092.1.**

Rome, 13/10/2023

  
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 Dr. Walter Quattrocchi  
 Person Responsible for Regulatory Compliance