

## BIOCOMPATIBILITY ATTESTATION

<b>SILBIONE LSR 4350 HC A&amp;B</b>
-------------------------------------

Elkem Silicones' Silbione® LSR 4350 is a member of a family of Silbione® LSRs for which biocompatibility testing has been conducted. Elkem's Silbione® LSR 4350 has been tested to the requirements of USP Class VI and/or ISO 10993 for skin contact healthcare applications or healthcare applications less than 30-day implantation. The specific biocompatibility tests conducted for this material are the following:

1. Cytotoxicity (ISO 10993-5)
2. Acute Systemic Toxicity (ISO 10993-11)
3. 7-Day Implantation study with macroscopic evaluation, without histopathology – (USP Class VI)
4. Ames mutagenicity (DMSO and saline extracts) (ISO 10993-3)
5. Intracutaneous Toxicity (USP Class VI)

LSR 4350 successfully passed all tests conducted. In addition to the tests described above, several additional tests were conducted on a substantially equivalent member of Elkem Silicones' Silbione® LSRs, Silbione® LSR 4340. Silbione® LSR 4340 successfully passed all tests conducted. The additional tests include:





1. Hemolysis (ASTM)
2. Pyrogenicity (USP Class VI)
3. Sensitization (allergenic) potential (LLNA Assay, ISO 10993)
4. 28-Day Implantation study (USP Class VI)

By analogy, Silbione® LSR 4350 also is considered to be non-hemolytic, non-sensitizing and non-pyrogenic.

As with all healthcare products, the manufacturer of the device must determine the suitability of the material and of the device utilizing the material. They are also responsible for assuring that the device utilizing the material is safe and effective for the prescribed use and meets all relevant regulatory requirements.

Certified by Elkem Silicones' Product Stewardship Department

Creation date: June 2019  
Valid until: June 2022

 EUROPE	 NORTH AMERICA	 LATIN AMERICA	 ASIA PACIFIC
<p><i>Elkem Silicones France SAS 21 avenue Georges Pompidou 69003 Lyon France</i></p>	<p><i>Elkem Silicones USA Corp. Two Tower Center Blvd Suite 1601 East Brunswick, NJ 08816-1100 USA</i></p>	<p><i>Elkem Silicones Brasil Ltda. Av. Duquesa de Goiás, 716 – 2º andar Cep. 05686-002. São Paulo/ SP Brazil</i></p>	<p><i>Elkem Silicones Hong Kong Co., Limited 29/F, 88 Hing Fat Street Causeway Bay Hong Kong</i></p>

*This is a computer-generated document that is valid without a signature.  
The information above is supplied in good faith and, to the best of our knowledge, is based on available sources believed to be reliable and accurate at the date of publication appearing above. This document and any information provided herein are for your guidance only.  
This document shall be valid until the validity limit date indicated above. However, because use conditions and applicable regulations may change with time, the requestor is responsible for determining whether the information is still appropriate and for asking for an update.  
The conditions of use by the requestor are beyond Elkem Silicones' control; therefore, the responsibility for appropriate and safe use of the above information lies with the requestor. Elkem Silicones shall not be responsible for any misuse and/or misapplication of the information in this document.*