



Publicly Certified and Authorized Expert for  
Toxicology of Cosmetics and Consumer Articles  
Attested by the Chamber of Commerce (IHK) „Mittlerer  
Niederrhein“

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**Certificate**  
**Toxicological Safety Assessment**  
for  
**Lunette Menstrual Cups**  
**PROJECT NO. 10.834**

**Sponsor:**

**Lune Group Oy Ltd  
Heli Kurjanen  
Kopsamontie 138  
FIN-35540 Juupajoki  
Finland**

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## 1 Subject of the toxicological safety assessment

The sponsor is manufacturing silicone menstrual cups, which are classified in Europe as consumer products, but in USA these comprise medical devices, class 2.

To prove the toxicological safety of the material a toxicological safety assessment has been conducted by the signatory authors based on analytical studies for extractable substances.

Since the full assessment report dated 02/12/2016 comprises confidential details about the composition of the material, the result is summarized by this certificate without such detailed information.

## 2 Overall conclusions

Based on the toxicological safety assessment together with its risk evaluation a relevant health risk for women, using the menstrual cups is not to be expected; the theoretically derived PDEs (Permitted Daily Exposures) for all extracted substances are well below the EDs (Exposure Doses).

Therefore, all extracted substances from the tested menstrual cups are classified to be of “*no toxicological concern*”.

## 3 Validity

This toxicological safety assessment is valid as long as no new relevant toxicological data with regard to the toxicity profile of any of the evaluated substances become available.

A re-evaluation may be mandatory at the latest, when through practical use significant adverse effects are reported to the attention of the sponsor, which may have been caused by the evaluated substances.

## 4 Expert Approval

The final conclusions and their derivations based on data from the sponsor, are certified by below signatory authors.

2016-12-15  
Dr. Joachim Haselbach  
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