

# EC Design Examination Certificate

## The Notified Body

**MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH  
Pilatuspool 2 – 20355 Hamburg – Germany**

herewith certifies that the design of the medical device(s):

- **Intra uterin pessary (IUP)**  
**with specifications listed in the appendix**

of the manufacturer:

**Primed Halberstadt Medizintechnik GmbH  
Straße des 20. Juli 1  
38820 Halberstadt  
Germany**

fulfills the below mentioned requirements of the **Council Directive 93/42/EEC**:

## Annex II, section 4

This certificate assumes that MEDCERT has to be informed about any changes of the approved design. Changes need further approval by MEDCERT.

For the placing on the market of medical devices covered by this certificate, a separate EC certificate of conformity according to Annex II without section 4 of Council Directive 93/42/EEC is required.

## This certificate is valid until 21 June 2022

Report No.: 11110PS18F  
Process No.: PP – 11110  
Certificate No.: 11110GB411191029D

Hamburg, 29 October 2019

  
MEDCERT Certification Body  
(Lorenz Runge)

The certificate is only valid when provided entirely with all of its pages.  
To verify the validity of this certificate, contact [info@medcert.de](mailto:info@medcert.de).

MEDCERT Identification Number: 0482

Form F10010009e EN / Rev. 5 / 2019.05.22



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
[www.zlg.de](http://www.zlg.de)  
ZLG-BS-237.10.15

## Appendix of EC Design Examination Certificate

Process No.: PP – 11110  
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### Specifications

Type	Article-No.
Gold Luna classic	13512
Gold Luna classic mini	13513
Gold Luna exclusive	13514
Gold Luna exclusive mini	13515

– End of appendix –

This appendix is integral part of the above-referenced certificate.  
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