

# DeltaMed

To whom it may concern

## History and clinical evaluation of Contragel® green (Medical device)

### 1. Application/Indication/Description

Contragel is a nonfat, water based gel, used with diaphragms, cervical caps and condoms.

The gelling results from cellulose in water.

When coated on a diaphragm or cervical cap, it acts as a mechanical barrier to sperm. The gel adheres the cervix and provides a secure fit due to adhesion.

The ingredients sodium lactate and lactic acid are also found as physiological components in the vaginal skin, serving to improve compatibility and preventing infections.

Due to the acidic pH they still appear slightly spermicidal.

Sorbic acid and vanillin are auxiliary substances that stabilize and prevent from malodor. Contragel green is latex-compatible.

In 1986, the PhD student Uwe Gieler from Marburg worked out a comparative analysis of different diaphragm gels. Contracep had equal results as, for example, Ortho Gynol Gel© or Ortho Creme©, both distributed in Germany by Janssen Cilag until 1988 and both containing Nonoxynol-9 as active component.

### 2. Specifications of ingredients:

All ingredients (with the exception of water) are applied with European pharmacopoeia (Ph.Eur. 5) quality.

### 3. Microbiological safety:

Contragel green is conserved. Nevertheless, it was subjected to a germ-exposure test, where no germination was detected. All facultative pathogenic germs died immediately after being inoculated.

### 4. History of product / clinical evaluation:

The product Contracep® green 60ml in tubes was produced and distributed to several European countries by the Dutch family planning organization NVSH (literary translated: "Dutch Association for Sexual Help"), comparable with PRO FAMILIA in Germany.

Later founded company of the NVSH association, called the Central Mideleen Depot (CMD) in The Hague resumed the composition and production in the 1980s.

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Foundations of composition (Attachment 1) and of test procedures of the requirements are obligatory for IPPF, the International Parenthood Federation, in London.

Until the termination of distribution in 2002, due to missing certificates, approx. 15,000 packages were produced annually. 8000 of those packages were exported to companies in Germany, including Kessel Marketing & Vertriebs GmbH.

(Source: Martin Kessel, Kessel Marketing & Vertriebs GmbH)

In 2004, DeltaMed GmbH took over the composition and produced exclusively for Kessel Marketing & Vertriebs GmbH. The product name was changed to "Contragel green". Since 2004, 60,000 packages have been produced and sold.

During the observation period of approx. 20 years, no complaints are known about serious side-effects or therapy failures. Our own statistics, as well as complaint-statistics from Kessel Marketing & Vertriebs GmbH in the years before 2004, verify this statement.

The notified body of DeltaMed GmbH joined the argumentation of clinical evaluation and demanded no additional, (clinical) studies for this product.

Contragel® green (once: "Contracep® green") is therefore considered an effective resource for the secure use with diaphragms and cervical caps.

**DeltaMed** GmbH  
Raiffeisenstrasse 8a • D-61169 Friedberg  
Tel. +49 (0) 6031 7283-0  
Fax +49 (0) 6031 7283-29  
[www.deltamed.de](http://www.deltamed.de) • [info@deltamed.de](mailto:info@deltamed.de)



Michael Zimmermann  
Pharmacist, QP  
Quality Management