

## **APPROVAL**

EC Directive 93/42/EEC; Annex V, Article 3
Quality Assurance System Production

Registration No.: OD 69244945 0001

Report No.: 28218120 001

Manufacturer: MEDCARE Gyógyszer és Gyógyászati Kereskedelmi

Kft.

Galváni u. 44. 1117 Budapest

Hungary

Scope: Manufacturing of dermal, vaginal and rectal

treatment system.

Products:

- Multifunctional shower head

- Intimate douche (vaginal and rectal)

- Capsules

**Date of expiry:** 09-08-2018

The Notified Body hereby authorizes the quality management system established and applied by the company mentioned above. The requirements of Annex V, Article 3 of the directive have been met. This approval is subject to periodic survelllance, defined by Annex V, Article 4 of the aforementioned EC Directive, and can be used by the company with the manufacturer's Declaration of Conformity.

Budapest, 17-09-2013

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**Notified Body** 

Zoltan Ambrus MD.

Certifier

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