

Date: 04/11/2020

## Declaration regarding Classification of Presto Gel (Gel & Suppositories) as Medical Devices

We, Dan Pharm Ltd. company, from Be'er Sheva, Israel, hereby declare that the Medical Devices:

- 1) Presto Gel
- 2) Presto Gel Suppositories

Are manufactured by us and are classified in accordance with Rule # 5 of Annex IX of the Medical Devices Directive MDD 93/42/EEC, as amended by the European Council Directive 2007/47/EC.

The products are classified as Medical Devices and not complementary or alternative medicine due to the following facts:

- The principal intended purpose of "Presto Gel" products (Gel & Suppositories) is to act in a mechanical manner for the treatment of Haemorrhoids and anal discomforts.
- Presto Gel products are Bacterial Blockers. They do not kill bacteria, but physically block the ability of harmful bacteria to penetrate the host cell.
- No pharmacological, metabolic, immunological or therapeutic actions are claimed, or intended, in or on the human body. The action of Presto Gel is purely mechanical in nature.
- Presto Gel Products produce a protective layer on the treated area, providing a safe physical barrier against microbial invasion and prevent contact with faecal acids and toxins which are the main cause of anal discomforts, such as: burning, itching, irritation and sensitivity. The bacteria is prevented from penetrating the host cell thanks to Presto Gel's bacterial blocking ability, which is mechanical in nature. The infection mechanism and bacterial development are blocked, resulting in the inflammation being controlled and hemorrhoid pain and anal discomforts being relieved.
- Presto Gel Products have **no** activity of: Cellular membrane disruption, Chemical reaction with downstream effects, Interaction with enzyme proteins, Interaction with structural proteins, Interaction with carrier proteins, Interaction with ion channels, Ligand binding to Hormone / Neuromodulator / Neurotransmitter receptors, whatsoever.

**DAN PHARM LTD**  
 Reg. No. 514017763  
 34/6 Ha'Bedil st., Beer Sheva-Isreal  
 Tel: +972-8-6235275, Fax: +972-8-6274244

**DANIEL SHOHET**  
 CEO

**ALEXANDRA ISAJEVA**  
 CHEMIST

**ALEXANDRA ISAJEVA**  
 QA Manager

QUALITY MANAGEMENT SYSTEMS  
 DAN PHARM LTD

Daniel Shohet  
 CEO  
 Dan Pharm Ltd.  
 04/11/2020

Alexandra Isajev (Chemist)  
 Quality Assurance Manager  
 Dan Pharm Ltd.  
 04/11/2020

