1.6 Declaration of conformity

Manufacturer:
PK Benelux BV
Vluchtoord 17
Uden
5406 XP
Netherlands

This statement confirms that the declaration of conformity is issued under the responsibility of the manufacturer.

We hereby declare that the manufactured CE marked medical device Irritable Bowel Syndrome and specified below, is covered by the "CE Marking and Conformity Certificate" under number Z/19/04409E and generic term bowel bulking agent, delivered by ECM, Bismarckstr. 106, 52066 Aachen, Germany, Notified Body Number 0481, and conform to the required technical documentation, in accordance with Annex V of the "EC Directive", the Council Directive 93/42/EEC of 14 June 1993, amended by Directive 2007/47/EC, concerning medical devices.

In addition PK Benelux BV ensures and declares that the manufactured CE marked products, as mentioned and falling within class IIa, meet the provisions of the EC-Directive which apply to them.

The Unique Device Identifier (UDI) will be added as soon as available.

This declaration is based on the application of the Quality System approved for the manufacture and final inspection of the products concerned, in accordance with Annex V of the EC-Directive. The conformity of the product quality assurance set out in Annex V, will be described in the said CE Marking of Conformity Certificate, issued and delivered by BSI Product Services, based on the harmonized standard ISO 13485:2016 under number MD 543099 issued on Feb 24th of 2018 by BSI UK, Notified Body Number 0086.

This Declaration Of Conformity covers products as specified in the list belonging to this declaration, and is valid for all products concerned, bearing the CE mark.

15-JUN-2020

PK Benelux BV, Uden

EU authorized representative: A. Steenbergen-Peters
QA/RA Manager

Product name
Irritable Bowel Syndrome
Prikkelbare Darm Syndroom
Gasterodoc Reizdarm Kapseln