



## 1.6 Declaration of conformity

PK Benelux BV  
Vluchtoord 17,  
5406 XP Uden,  
The 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 Fungal nail and products as specified in the Product List on the Cover Sheet of this Technical Construction File, are covered by the "CE Marking and Conformity Certificate" under number Z/19/04409E and generic term 'Dermatological Use', 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 24<sup>th</sup> of 2018 by BSI UK, Notified Body Number 0086.

This Declaration of Conformity covers products as specified in the Product List on the Cover Sheet of this Technical Construction File, and is valid for all products concerned, bearing the CE mark.

Date: 17-09-2020

  
PK Benelux BV  
Mrs. A. Steenberg-Peters  
QA/ RA Manager

Product name:

Fungal nail, bottle 5 or 10 ml;  
Fungal nail pen, 4 ml  
Naildoc Rapid 5 ml  
Naildoc Rapid Treatment Pen 4ml