

Manufacturer's Declaration of Conformity

(in accordance with ISO/IEC 17050-1)

Issuer's name : Medeco BV
Chamber of Commerce Registration # 23038479

Issuer's address : Alexander Flemingstraat 2
3261MA Oud Beijerland
The Netherlands

Object of the declaration : Medical Devices for use in diabetes care

UMDNS Code : See attached Product list

Classification : According to MDD Annex IX, see attached Product list

Conformity assessment : MDD Annex II

Validity : This declaration of conformity is valid at least during the lifetime of the products concerned. The declaration will be updated in case of changes in the product range and after issuance of a new product or quality system certificate.

Hereby Medeco BV declares that the distributed products as specified in the annexed product list meet the provisions of the MDD 93/42/EEC Medical Device Directive: Council Directive 93/42/EEC concerning medical devices June 14th, 1993 as amended by directive 2007/47/EC and comply to all harmonized standards which are applicable to the products, as published in the Official Journal of the European Union. Medeco BV further declares that it is exclusively responsible for this declaration of conformity.

Additional information

Notified Body : BSI, Notified Body Number 2797
Say Building, John M. Keynesplein 9,
1066 EP Amsterdam, The Netherlands

CE certificate : CE 607662

First Issue Date certificate : 24 June 2016

Validity : 26 May 2024

This documentation is supported by the Quality Management System certification based on the harmonized standard EN ISO 13485:2016, Quality Management System Certificate with reference numbers: MD 644507, issued for the 1st time on 20 June 2016, and delivered by BSI UK. The applied standards for this family of products are maintained in the Technical Dossier.

Oud Beijerland, 14 December 2020

Name : A.S. Kastelein – de Visser
Function : Manager QA
Medeco BV

Signature :



UMDNS	REF nr	Article nr	Name	Class	Rule
24-026	5065	3038457	Klinion Soft fine Plus 0,23mm 32G* 4 mm	Ila	6
24-026	5064	3038456	Klinion Soft fine Plus 0,23mm 32G* 5 mm	Ila	6
24-026	5068	3038459	Klinion Soft fine Plus 0,23mm 32G* 6 mm	Ila	6
24-026	5069	3038460	Klinion Soft fine Plus 0,23mm 32G* 8 mm	Ila	6
24-026	5066	3038458	Klinion Soft fine Plus 0,25mm 31G* 5 mm	Ila	6
24-026	5060	3038453	Klinion Soft fine Plus 0,25mm 31G* 6 mm	Ila	6
24-026	5061	3038454	Klinion Soft fine Plus 0,25mm 31G* 8 mm	Ila	6
24-026	5063	3038455	Klinion Soft fine Plus 0,33mm 29G* 12 mm	Ila	6
24-026	5071	3051658	Sample Box Klinon Soft fine Plus 0,25mm 31G* 8 mm	Ila	6
24-026	5070	3051659	Sample Box Klinon Soft fine Plus 0,25mm 31G* 6 mm	Ila	6
24-026	5075	3060348	Klinion Soft fine Plus 0,23mm 32G* 4 mm	Ila	6
24-026	5074	3060349	Klinion Soft fine Plus 0,23mm 32G* 5 mm	Ila	6
24-026	5078	3060371	Klinion Soft fine Plus 0,23mm 32G* 6 mm	Ila	6
24-026	5079	3060374	Klinion Soft fine Plus 0,23mm 32G* 8 mm	Ila	6
24-026	5076	3060370	Klinion Soft fine Plus 0,25mm 31G* 5 mm	Ila	6
24-026	5080	3060373	Klinion Soft fine Plus 0,25mm 31G* 6 mm	Ila	6
24-026	5081	3060375	Klinion Soft fine Plus 0,25mm 31G* 8 mm	Ila	6
24-026	5073	3060376	Klinion Soft fine Plus 0,33mm 29G* 12 mm	Ila	6