

EC DECLARATION OF CONFORMITY

Manufacturer: Kepler Vision Technologies BV.
 Deymanstraat 18F,
 1091 SE Amsterdam,
 the Netherlands

Description of device concerned : Kepler Night Nurse (KNN)

Version number: Version 1

Variants: Release at date of sign off of this DoC: 1.2.27

The releasenummer convention for release x.yy.zzzz is as follows

x	[Major]	Representative for Intended Use	The Competent Authority will be notified on changes to the intended use. The Regulatory File will be updated accordingly.
		Representative for version number	
y	[Minor]	Representative for User Interface	The Regulatory File will be updated accordingly on changes affecting the User Interface.
z	[Patch]	Representative for Technical Changes	The Regulatory File will be updated accordingly on technical changes.

MDD Classification rule Class I per MDD, Annex IX , Rule 12

Conformity Assessment procedure: MDD Annex VII

KNN is in conformity with the relevant sections of the following harmonised standards	Harmonized Standard	Title	Version
	EN 15223	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements	2016
	EN 1041	Information supplied by the manufacturer of medical devices	2008 +A1:2013
	EN ISO 14971	Medical devices – Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)	2012
	EN 62304	Medical device software – Software life-cycle processes – EC 62304:2006	2006/AC2008
	EN 62366	Medical devices – Application of usability engineering to medical devices – IEC 62366:2007	2008

Statement:

I, the undersigned, hereby declare that KNN, meet the applicable provisions of the EC Directive 93/42/EEC which apply to them.

This declaration applies to all devices specified above distributed from the signature date forward.

Validity DoC from Date [YYYYMMDD]:	Place:	Date [YYYYMMDD]:
20201019	Amsterdam	20201008

Name: **H.M.G. Stokman**

Function: **CEO**


