

HAEQUEO	Product Technical Dossier	Rev.02	
	cross-linked sodium hyaluronate 2,5% intra-dermal use	Issued on: 30.01.2016	

Essential Requirements

The list of harmonized standards and rules are applied by MEDIVICE to operate with the product are listed in the below table:

Document number	Document title
ISO 13485:2003	Quality Systems – Medical Devices
MDD 93/42/EEC	EU Medical Device Directive
MDD 2007/47/EEC	EU Medical Device Directive (amendment of MDD 93/42/EEC)
D.Lgs. 46/97	Recepimento italiano della MDD 93/42/EEC
MEDDEV 2.12-1 rev 5	Guidelines on a Medical Devices Vigilance System
EN 980:2003	Graphic symbols for the labeling of medical devices
ISO 14155-1:2013	Clinical investigation of medical devices for human subjects Part 1-General Requirements