EC Declaration of Conformity

Manufacturer	GONOTEC Gesellschaft für Meß- und Regeltechnik mbH GSG-Hof Reuchlinstraße 10-11 10553 Berlin / Germany	
Product series	OSMOMAT 3000 Automatic Cryoscopic Osmometer	
Cat.No.:, Type	32.00000	OSMOMAT 3000
	32.10000	OSMOMAT 3000 D
	32.02000	OSMOMAT 3000 M
	32.12000	OSMOMAT 3000 D-M
	32.B	OSMOMAT 3000 basic
Nomenclature Systems	GMDN 57854 / UMDNS 12-842	

Applied harmonized standards:

Usability/ Risk	IEC 62366-1
	IEC 62304
	ISO 14971
Disposal	RoHS Directive 2011/65/EU
	WEEE Directive 2012/19/EU (Reg.Nr.:DE65424410)
EMC	IEC 61000-3-2
	IEC 61326-1
	IEC 61326-2-6
Safety	IEC 61010-1
	IEC 61010-2-101

Other normative documents:

DIN EN ISO 13485
Ph.Eur. 2.2.35. / USP <785>

CE

We hereby declare on our responsibility that the medical device described above, both in its basic design and construction and in the version marketed by us, meets all the provisions of the Directive 98/79/EC for In Vitro Diagnostic which applies to it; using Annex III as the conformity assessment procedure. The mark of conformity has been applied to the product.

This declaration of conformity applies to above listed product placed on the EU market after:

Date Berlin, 2018-11-06

Jan Celinšek (General Manager)