EC Declaration of Conformity

Manufacturer	GONOTEC Gesellschaft für Meß- und Regeltechnik mbH GSG-Hof Reuchlinstraße 10-11 10553 Berlin / Germany	
Product series	Calibration Standard/ Reference Solution for in vitro diagnostic use with all osmometers	
Cat.No.:, Type	30.9.0100	100 mOsmol/kg NaCl/H_20
	30.9.0020	300 mOsmol/kg NaCl/H_20
	30.9.0500	500 mOsmol/kg NaCl/H_20
	30.9.0850	850 mOsmol/kg NaCl/H_20
	30.9.2000	2000 mOsmol/kg NaCl/H_20
	30.9.0290	OSMOREF® 290 mOsmol/kg NaCl/H_20
Nomenclature Systems	EDMA 11 50 03 03 / UMDNS 17-031 / GMDN 52885	
	Applied harmonized standards:	
Usability/ Risk	DIN EN ISO 15223-1 DIN EN ISO 18113-2 ISO 14971	
Disposal	REACH Directive 1907/2006/EU	
	Other normative documents:	
	DIN EN ISO 13485 Eur.Ph./USPC GMP	
Reference material	Solutions are traceable to standards prepared from NIST Standard Reference material (SRM 919b Sodium Chloride)	

CE

We hereby declare on our responsibility that the medical devices 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)