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|-----------------------------------|--------------------------------------|-----------|-------------|
| DAC-SpectroMed S.R.L.<br>Chisinau | Declaration of EC-Conformity         | File No.  | F-PS-10-05  |
|                                   |                                      | Rev. No.  | 2           |
|                                   | Product: HbA1c Calibrator (4 levels) | Rev. Date | 07-16-2019  |
|                                   |                                      | Doc.No    | STD-DCE-359 |
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## DAC-SpectroMed SRL

Nicolae Testemitanu str. 37, MD-2025, Chisinau, Republic of Moldova

hereby declares under its own responsibility that the *in-vitro diagnostics* medical devices:

### HbA1c Calibrator (4 levels)

REF 1103H2 4 x 0,5 ml

- are classified as not listed in Annex II of the EC Council Directive 98/79/EC from 27<sup>th</sup> October 1998 on in-vitro diagnostic medical devices;
- conform to the relevant provisions of the EC Council Directive 98/79/EC from 27<sup>th</sup> October 1998 on in-vitro diagnostic medical devices.

Harmonized standards applied:

EN ISO 9001:2015

EN ISO 14971:2012

EN ISO 18113-1:2011

EN ISO 18113-2:2011

EN ISO 23640:2011

EN ISO 13612:2002

EN ISO 15223-1:2012

EN ISO 13485:2016

DAC-SpectroMed SRL has a Quality System in place based on EN ISO 9001:2015 and EN ISO 13485:2016, issued by the IQNet&SRAC.

Our Authorized Representative in EU is Qarad B.V., with address at Flight Forum 40, 5657 DB Eindhoven, The Netherlands.



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16.07.2019

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16.07.2019