



Medical Device Regulation (2017/745/EU) Statement

Company Name: EDAC, Inc.
Company Address: 161 Alden Rd. Units 7 & 8, Markham ON, Canada, L3R 3W7
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This letter is to certify the above-listed product(s) produced by the above-mentioned company, meet(s) the MDR substance requirements of not containing substances classified as CMR 1A or 1B, and/or Endocrine-Disrupting Substances (EDS) at levels greater than 0.1% w/w within each homogeneous material. The list of CMR 1A or 1B and Endocrine-Disrupting Substances can be found at:

http://www.greensofttech.com/PE21/Welch_Alyn/MDR_...

The above-mentioned company also declares the following:

	Yes/No	Note
Presence of tissues or cells of human origin or their derivatives	No	If yes, please provide the name and location of the substance.
Presence of tissues or cells of animal origin or their derivatives	No	If yes, please provide the name of the substance and confirmation of compliance to (EU) No 722/2002
Presence of Latex	No	
Presence of Medicinal substances	No	

Authorized Signature:

Name: Reza Esmaeili

Title: Quality Engineer

Date: 1/21/2020