AMITRON

PRINTED CIRCUIT BOARDS

2001 Landmeier Road ▪ Elk Grove Village, IL ▪ (847) 290-9800 ▪ www.Amitron.com

Declaration of Conformity
EU Medical Device Regulation (2017/745)

The European Union (EU) Medical Device Regulation (MDR) 2017/745 came into full effect on
May 26, 2021, replacing the EU Medical Devices Directive (MDD).
Under section 10.4.1 of the legislation text, the usage of substances classified as CMR 1A/1B EU Regulation 1272/2008 (Classification, Labelling and Packaging of Chemicals) or Endocrine-Disrupting substances identified in EU Regulation 1907/2006 (REACH: Registration, Evaluation, Authorisation, and Restriction of Chemicals) or EU Regulation 528/2012 (Market and Use of Biocidal Products) are restricted to 0.1% (w/w) in medical devices.

This declaration letter certifies the compliance status of all bare printed circuit boards manufactured by Amitron Corp. w.r.t EU MDR substance requirements & devices incorporating materials of biological origin.

EU MDR substances present above regulated limits: No

Please keep in mind that the information being provided regarding the substances contained in these product(s) is solely based on information provided by suppliers or producers of the raw materials. We have not conducted any tests to determine the presence of these substances.

We will continue to monitor all the changes to the legislation and update this declaration to reflect those changes.

More about EU MDR: https://eumdr.com/

Authorized Name: Charlie Savaliya **Date: 07/25/2023**

Charlies

Director of Quality
Amitron Corporation
2001 Landmeier Road, Elk Grove Village, IL 60010