EU Declaration of Conformity

Section I – General Details

Manufacturer's Name:	Curesponse Ltd.
Manufacturer's Address:	4 Oppenheimer Street, Ha'Ogen B Building, 14th Floor, Rehovot, Israel
Authorized EU Representative Name:	Propharma BV
Authorized EU Representative Address:	Schipholweg 73 – 75 2316 ZL Leiden The Netherlands
Name of the IVD:	cResponse™
Intended Use:	The intended use of the cResponse™ platform is to provide the oncologist with information concerning the relative effect of different anti-cancer drugs on the patient's tumor

Intended User:	cResponse™ test is performed only in authorized Curesponse laboratories, under strict supervision
IVD Directive Category:	General
Notified Body:	Not applicable
CE Certificate Reference:	Not applicable
IVD Directive Conformity Assessment Route:	Annex III (EC Declaration of Conformity)

This declaration of conformity is issued under the sole responsibility of Curesponse Ltd. We hereby declare that the in vitro diagnostic medical device (IVD) specified above meets the applicable regulatory requirements in accordance with 98/79/EC In Vitro Diagnostics Device Directive (IVDD) which has been given effect in UK law through Medical Devices Regulations 2002 (SI 2002 No 618, Part IV, as amended) (UK MDR 2002).

All supporting documentation is retained at the premises of the manufacturer.

Signature:

Place and date of issue: 19/0572022

Guy Neev

Curesponse Ltd.
515737328

Name: Guy Neev

Position: CEO

Section II – Applicable Standards

This present declaration is also in conformity with the following European and International standards:

Standard / Document Name	Description
98/79/EC	Directive of the European Parliament and of the council of 27 October 1998 on in vitro diagnostic medical devices (IVDD)
ISO 15189:2012	Medical laboratories — Requirements for quality and competence
ISO 13485:2016	Medical devices — Quality management systems — Requirements for regulatory purposes
ISO 14971:2019	Medical devices — Application of risk management to medical devices
ISO 20916:2019	In vitro diagnostic medical devices – Clinical performance studies using specimens from human subjects – Good study practice
IEC 62304: 2006 Amd 1: 2015	Medical Device Software – Software Life cycle processes
ISO 15223-1:2021	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements
ISO 18113-1:2009	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 1: Terms, definitions and general requirements
ISO 18113-2:2009	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 2: In vitro diagnostic reagents for professional use
ISO 23640:2011	In vitro diagnostic medical devices — Evaluation of stability of in vitro diagnostic reagents
IEC 62366-1:2015/AMD 1:2020	Medical devices — Part 1: Application of usability engineering to medical devices
EN 13612/AC:2002	Performance Evaluation of In Vitro Diagnostic Medical Devices
REACH	Regulation (EC) No 1907:2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH),

	establishing a European Chemicals Agency
MEDDEV 2.7/1 Rev 4:2016	Clinical Evaluation: A guide for manufacturers and notified bodies under directives 93/42/EEC and 90/385/EEC
MEDDEV 2.12/1 Rev 8:2013	Guidelines on a Medical Devices Vigilance System
MEDDEV 2.14/3 Rev 1:2007	In Vitro Diagnostic Guidance: Supply of Instructions For Use (IFU) and other information for IVD Medical Devices
MEDDEV 2.14/1 Rev 2:2012	Guidelines on medical devices, IVD Medical Device Borderline and Classification issues

Section III – Product Listing / Schedule

Name / Description	**GMDN Code and Description**
cResponse™	61231 - Cancer risk assessment interpretive software IVD An in vitro diagnostic interpretive software program intended to be used in the assessment of risk for developing cancer (e.g., breast, ovarian, prostate, lung, liver, gastric, pancreatic, colorectal). It uses specific algorithms to combine and correlate patient demographics, clinical observations, and the in vitro diagnostic results of the qualitative and/or quantitative detection of one or multiple cancer-specific biomarkers in a clinical specimen to establish an individual risk score that may be used to guide patient management.