

4 Apr 2025

Exact Imaging REACH Declaration

Please be advised that the Exact Imaging products listed below meet the criteria for Authorization under the European Union's REACH Regulation (EC) No 1907/2006 (Dec 2024 update) and RoHS 2 Directive 2011/65/EU of the European Parliament and of the council of 8 June 2011 on the Restriction of the use of certain hazardous substances in electrical and electronic equipment; it is not intentionally manufactured or formulated with cadmium, hexavalent chromium, lead, mercury, polybrominated biphenyls, or polybrominated diphenyl ethers.

Exact Imaging does not deliberately add any substances in the Candidate List of Substances of Very High Concern published by ECHA to the products listed below, nor are any such substances present in the products above 0.1% (w/w).

Part	Reference	Model
6127	EV-SYS-220	220V ExactVu micro-ultrasound system
6437	EV-SYS-120	120V ExactVu micro-ultrasound system
6089	EV-29L	EV29L Transrectal Transducer
6087	EV-9C	EV9C Transrectal Transducer
6088	EV-5C	EV5C Abdominal Transducer
6656	EV-BIOGR	Reusable transrectal needle Guide for EV29L Transducer, 18 GA
6868	EV-BIOG-R16	Reusable transrectal needle Guide for EV29L Transducer, 16 GA
6894	EV-29L-TRK-24	EV29L sterile transrectal needle guide with sheath (24-pack)
6904	EV-29L-TPK-24	EV29L sterile transperineal needle guide with sheath (24-pack)

Sincerely,



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