

EU Declaration of Conformity

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Issuer and manufacturer

Distran AG
Breitensteinstrasse 96
8037 Zürich
Switzerland

Product

Equipment type: Ultrasound camera
Model name: Ultra PRO X v3
Marketing name: Ultra PRO X
Serial numbers: 50XYYZZZZZ

Product photo



We declare that the product described above, to which this declaration of conformity refers to, is in conformity with the essential requirements of the the following legislations:

- Equipment and protective systems intended for use in potentially explosive atmospheres Directive 2014/34/EU for Category 3 equipment
- Radio Equipment Directive 2014/53/EU
- Electromagnetic Compatibility (EMC) Directive 2014/30/EU
- RoH82 Directive 2011/65/EU

through the technical standards/specifications specified below:

EN IEC 60079-0: 2018	Explosive atmospheres – Part 0: Equipment – General requirements
EN 60079-11: 2012	Explosive atmospheres – Part 11: Equipment protection by intrinsic safety "i"
EN 61010-1: 2010	Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements

EN 61326-1:2013	Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 1: General requirements
EN 62479:2010	Assessment of the compliance of low power electronic and electrical equipment with the basic restrictions related to human exposure to electromagnetic fields (10 MHz to 300 GHz)
EN 301 489-1 V2.2.0.	Electromagnetic compatibility and Radio spectrum Matters (ERM); Electromagnetic Compatibility (EMC) standard for radio equipment and services; Part 1 : Common technical requirements.
EN 301 489-17 V3.1.0	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for Broadband Data Transmission Systems; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU
EN 301 489-19 V2.1.0	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 19: Specific conditions for Receive Only Mobile Earth Stations (ROMES) operating in the 1,5 GHz band providing data communications and GNSS receivers operating in the RNSS band (ROGNSS) providing positioning, navigation, and timing data; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU
EN 300 328 V2.1.1 (2016-11)	Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU
EN 301 893 V2.1.1	5 GHz RLAN; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU
EN 303 413 V1.1.1	Satellite Earth Stations and Systems (SES); Global Navigation Satellite System (GNSS) receivers; Radio equipment operating in the 1164 MHz to 1300 MHz and 1559 MHz to 1610 MHz frequency bands; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU

Technical Compliance File Held by

Distran AG
Breitensteinstrasse 96
8037 Zürich
Switzerland

Signed for and on behalf of Distran AG

Name: Joel Busset, CTO

Zürich

Place of issue

31.12.2020

Date of issue



DISTRAN AG
Breitensteinstrasse 96
8037 Zürich
Switzerland

Authorized signature