# Adaptiiv Software – Regulatory Overview

## Product Indications For Use

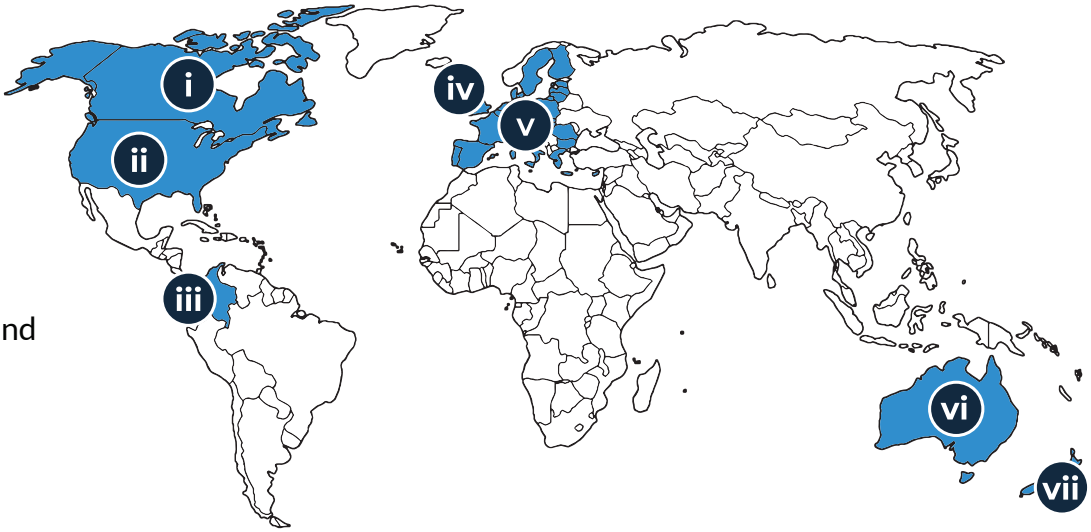
Adaptiiv software is indicated for use as an accessory to a radiation therapy treatment planning system (TPS) to design patient-specific 3D-printable objects intended for use during external beam photon or electron radiation therapy, or brachytherapy.

Adaptiiv Medical Technologies Inc. holds valid MDSAP and EC Certificates for: "Design and manufacture of medical device software enabling in-house design and 3D printing of radiation therapy treatment accessories."

## Product Availability

Adaptiiv software has received required regulatory clearance and can be sold and distributed in the following jurisdictions:

i. Canada
ii. United States[1]
iii. Columbia
iv. United Kingdom[2]
v. European Union[2] and Switzerland
vi. Australia
vii. New Zealand




[1] **FDA 510(k) Clearance –** the device (i.e. Adaptiiv software) is substantially equivalent to a device already on the market.
[2] **CE Mark –** product (i.e. software) has been assessed by the manufacturer and Notified Body and was deemed to meet EU safety, health, and environmental protection requirements.

## Considerations For Use

- Adaptiiv is not cleared or approved for the manufacture or distribution of hardware, parts, and materials.
- Recommended printer-filament sets are not covered under Adaptiiv's clearance. Adaptiiv software is validated for use with the specific printer-filament set, however, printing instructions provided by Adaptiiv are recommendations only.
- It is up to a prescribing physician to quality control and accept the printed radiation therapy accessory and ensure the part's suitability for the treatment.

**DISCLAIMER** Adaptiiv On Demand solution is currently under regulatory review, product clearances required for distribution or sale in the aforementioned jurisdictions are pending.