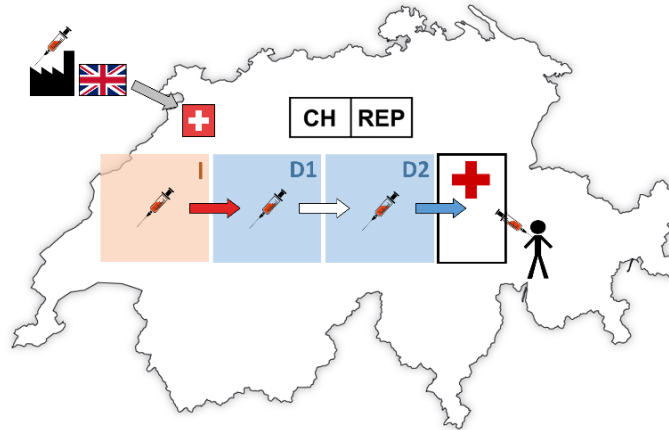


SWISS AUTHORIZED REPRESENTATIVE (CH REP)

SPECIAL PROPOSAL FOR BIVDA MEMBERS



Following Brexit, UK manufacturers of IVDs and medical devices can only place their products on the Swiss market after appointing an authorized representative based in Switzerland. confinis is a leading consulting company for medical devices, in-vitro diagnostics and combination products - it fulfils all legal requirements for Swiss authorised representatives (CH-REP) according to the current regulations.

<u>Service</u>	<u>Cost</u> (in Swiss Francs - CHF)
CH REP Service (including appointment of two PRRCs, Person Responsible for Regulatory Compliance)	2,000.00 (annual; 50% discount on standard price)
On-boarding (including the initial communication to Swissmedic by confinis)	1,250.00 (one time; 20% discount on standard price)
Analysis of technical documentation	200.00 (per IVD class A / B technical doc.) 400.00 (per IVD class C technical dossier) 600.00 (per IVD class D technical dossier)
Administrative costs required by Swissmedic	Assessed on a case-by-case basis
Other activities related to acting as an agent (e.g. communications to Swissmedic of incidents, recalls, registrations)	200.00 (hourly rate)
Further specific activities for individual associates	Ad hoc quote



For further information, please write to: **ch-rep@confinis.com**