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DECLARATION OF CONFORMITY

We, the undersigned **POLICHEM S.A.** Via Angelo Maspoli, 11, 6850 Mendrisio, Switzerland, as manufacturer according to Regulation (EU) 2017/745 of the medical devices in object, hereby

DECLARE

that the following product:

SATIVEX® Assistance Device

Basic UDI-DI (GMN): 8430308000001T9

(see Annex 5 list for codes, brand names and countries)

Is classified as a **class I** medical device according to Rule 5 of Annex VIII of the Regulation (EU) 2017/745 Regulation, and subsequent amendments and upgrades,

Its intended purpose is to support multiple sclerosis spasticity patients, with hands/upper limbs impairment, in self-administering the medicinal product Sativex® oromucosal spray.

Has been manufactured in accordance with the technical documentation required in Regulation (EU) 2017/745, Annexes II and III, and satisfies the General Safety and Performance Requirements defined in Annex I of Regulation (EU) 2017/745 Regulation, as amended.

We also declare that the CE marking of Sativex® *Assistance Device* has been applied according to:

EC Declaration of conformity for class I medical devices, according to Annex IV of Regulation (EU) 2017/745 and subsequent amendments and upgrades.

We further declare that this Declaration of Conformity is issued under the sole responsibility of Polichem SA and that procedures for post-marketing surveillance and product traceability applies.

TF-22-11-01_Declaration of Conformity_signed_MAY 2020

ELECTRONIC SIGNATURES

Signed by	Meaning of Signature	Server Date (dd-MMM-yyyy HH:mm 'GMT'Z)
Juan Francisco Raya Cortes	Management Approval	15-May-2020 07:30 GMT+0

SAP CODE	DESCRIPTION	COUNTRY	DISTRIBUTOR	SHIPMENT INSTRUCIONS*	NOTES
60007151	Sativex assistance device EU	Austria	Almirall Hermal GmbH	ROAD Controlled Temperature (+15° / +25° C) ADR LQ	Common multilingual pack for all the countries, containing the device and a booklet with the instructions for use in all the required languages. (see below)
		Belgium	Almirall N.V.		
		Denmark	Almirall ApS		
		Germany	Almirall Hermal GmbH		
		Italy	Almirall S.p.A.		
		Ireland	Almirall ApS		
		Norway	Almirall ApS		
		Portugal	Almirall Produtos Farmacêuticos, Lda.		
		Spain	Almirall S.A.		
		Sweden	Almirall ApS		
		Switzerland	Almirall AG		

Languages on the Label and IFU: DA, DE, EN, ES, FR, IT, NL, NO, PT and SV

TF-22-05-Product Codes_rev 01_FEB 2020

ELECTRONIC SIGNATURES

Signed by	Meaning of Signature	Server Date (dd-MMM-yyyy HH:mm 'GMT'Z)
Javier Segado Ferran	Regulatory Affairs Approval	05-Feb-2020 10:07 GMT+0
Claudio Marchelli	Quality Assurance Approval	05-Feb-2020 10:51 GMT+0
Juan Francisco Raya Cortes	Management Approval	05-Feb-2020 11:39 GMT+0