

中华人民共和国医疗器械注册证

注册证编号：国械注进20162215144

注册人名称	IMPETO MEDICAL
注册人住所	17,rue Campagne Premiere FR-75014 PARIS
生产地址	17,rue Campagne Premiere FR-75014 PARIS
代理人名称	北京英佩特医疗器械有限公司
代理人住所	北京市朝阳区工人体育场北路4号81号楼一层107室，二层229室
产品名称	电导分析仪 Digital Chronoamperometric Analyzer
型号、规格	eZscan
结构及组成	产品由EZSCAN主机（已安装软件，代码为eZMU）、手部电极板和连接线（代码为APH2）、脚部电极板和连接线（代码为APF2）和一条电源线组成。软件版本号：V2.40c
适用范围	用于测试皮肤的电反应，测量汗腺在电化学激活作用下释放氯离子的能力，通过导电性来评估周围神经病变。
附件	产品技术要求
其他内容	/
备注	

审批部门：国家食品药品监督管理总局

批准日期：二〇一六年十二月二十八日

有效期至：二〇二一年十二月二十七号



Medical device registration certificate of the People's Republic of China

Registration certificate number : 国械注进 20162215144

Registrant name	IMPETO MEDICAL
Registrant residence	17,rue Campagne Premiere FR-75014 PARIS
ADDRESS OF MANUFACTURING SITE	17,rue Campagne Premiere FR-75014 PARIS
Agent's Name	Beijing IMPETO medical instrument co., LTD
Agent residence	First floor room 107, second floor room 229, Building 81, Stadium Road No.4, Chaoyang District, Beijing, China 100027
product name	Digital Chronoamperometric Analyzer
Models, specifications	eZscan
structure and composition	Host (software embedded, code: eZMU), hand electrodes and a connecting line (code APH2), foot electrodes and a connecting line (code APF2) and one power line. Software version: V2. 40c.
scope of application	"eZscan is used to measure the electronic response of the skin, to measure the ability of sweat glands to release chloride ion in response to an electrochemical stimulation. It can be used to assess peripheral neuropathy through electrochemical skin conductance.
attachment	Product technical requirement
others	/
remarks	

The examination and approval department: the state food and drug administration

Valid date from 2016-12-28 to 2021-12-27