



ISET S.r.l. Unipersonale

Sede Legale e Uffici

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Cap. soc. i.v.

€ 10.200,00

Cod. Fisc. e P.IVA Reg. Imprese

02 332 750 369

REA

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Cap. soc. i.v.

MN 0221098

CERTIFICATE

Certificat - Certificado- Сертификат - Zertifikat - 證書

- 1) **APPLICANT:** (who finally puts the product on the market)

Hefei DX Medical Co., Ltd

1101-1108 Room, Liheng Industrial Plaza, Economic Development Zone, Hefei, Anhui, China

- 2) **CERTIFICATE NO.:** ISETC.003720200331

FILE REFERENCE: MICEZ-20(02)-032531-EMC

- 3) **ISET MARK:**



- 4) **CAUTION ABOUT CE MARKING** (Instruction for the Applicant who puts the product on the EU market):



The label of the CE Marking on the left side should be not less than 5mm height. CE Marking and EC Declaration of Conformity are duties for the manufacturer or its applicant who puts the product on the market. This one is responsible to start the CE marking and certification procedure as required by the legislation in force. Only for the products which are compulsorily included into specific Directives or Regulations will be necessary to appoint a Notified Body.

- 5) **TYPE OF PRODUCT:** Medical Concentrator With Small Size

MODEL(S): ZY-5AW,ZY-1JW,ZY-3AW,ZY-3BW,ZY-3FW,ZY-1AW,ZY-1BW,ZY-2AW,ZY-2BW,ZY-5B,ZY-5F,
ZY-5FW,ZY-1S,ZY-2S,ZY-3S,ZY-1SW,ZY-2SW,ZY-3SW,ZY-1F,ZY-2F,ZY-1FW,ZY-2FW,
ZY-1HW,ZY-2HW,ZY-3HW,ZY-5HW,ZY-2JW,ZY-3JW,ZY-1EW,ZY-2EW,ZY-3EW,
ZY-5EW,ZY-3KW,ZY-3KW,ZY-2ZW,ZY-3ZW,ZY-5ZW,ZY-10ZW,ZY-10FW,ZY-1Z,
ZY-1ZW,ZY-1R,ZY-1RW,WHZ-1802 ,WHZ-2802,WHZ-3802,WHZ-5802/ZY-10AW

- 6) **LIST OF DIRECTIVES / REGULATIONS /STANDARDS** (as declared by the manufacturer itself)

Electromagnetic Compatibility 2014/30/EU, EN 60601-1:2006+A12:2014, EN 60601-1-2:2015

- 7) **NOTE:** The applicant is aware about the contents and information included in the ModCOM04.06 Regulation for this type of Certificate that is considered totally accepted. The latest revision of the Regulation is available and can be downloaded from the website www.iset-italia.eu. This document is not referred to any evaluation that could be considered as included in the scope of the activities covered by the standard BS EN ISO/IEC 17065:2012 or European Regulation 765/2008.

- 8) **REMARK:** Certificate is issued on voluntary application from the Client and it gives to the applicant the right to use and affix the ISET Mark (at point 3) on their products, even if it doesn't imply any assessment on the safety and compliance of the product. ISET declares that the only scope of the assessment is to verify the existence of the declaration issued by the manufacturer or an applicant under its own responsibilities.

- 9) **DATE OF ISSUE:** 30/03/2020

EXPIRY DATE: 29/03/2025

- 10) **SIGNATURE:** Xiao Ming

(On behalf of the Legal representative)

