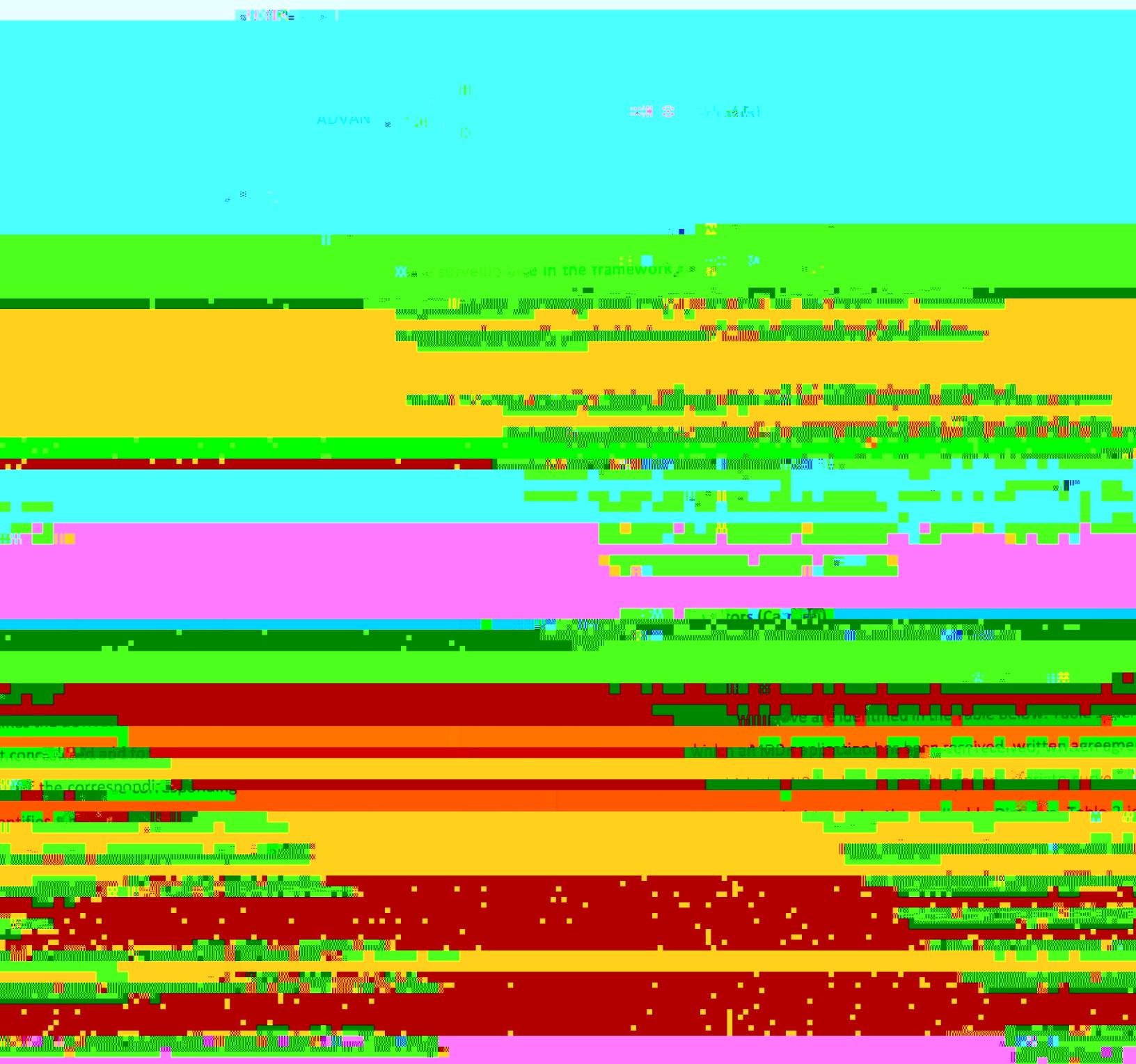


April 2024





20 March 2023, without having been withdrawn by the customer.

The certification is valid for the following scope:

Manufacture of medical devices for the diagnosis and treatment of diseases.

Manufacture of medical devices for the diagnosis and treatment of diseases.

Manufacture of medical devices for the diagnosis and treatment of diseases.

Reference to the other conditions specified in Article

Medical Devices

NSA

For confirmation

If you have any questions about this letter, please email Medical Devices (UK).



Article 1: Products covered by this letter and for which the NB is also responsible, surveillance under the corresponding deviated or the applicable Directive:

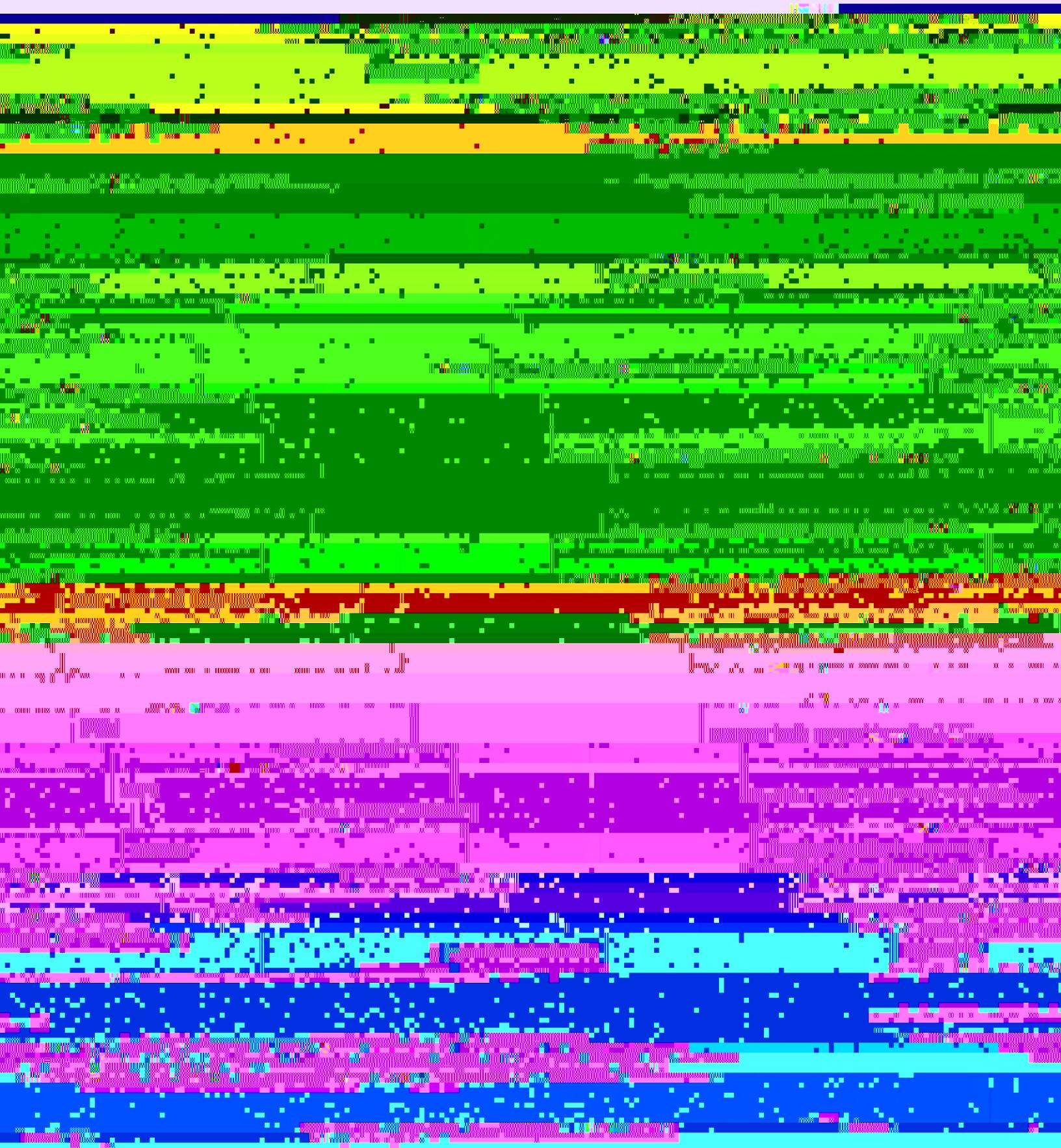
MDR Device

M-1

Device name

www.english-test.net

Manufacturer's Declaration



May 2024

W. 1. 1. 1.

namely by meeting the following conditions:

> Directive Conditions listed above or in the attached

allowable elsewhere

allowable elsewhere

26 May 2024

1. We do not intend to issue a new application for the declaration of conformity associated with the declaration of conformity issued on 29 March 2024.

allowable

2. We do not intend to issue a new application for the declaration of conformity associated with the declaration of conformity issued on 29 March 2024.

allowable

3. We do not intend to issue a new application for the declaration of conformity associated with the declaration of conformity issued on 29 March 2024.

allowable

4. We do not intend to issue a new application for the declaration of conformity associated with the declaration of conformity issued on 29 March 2024.

allowable

5. We do not intend to issue a new application for the declaration of conformity associated with the declaration of conformity issued on 29 March 2024.

allowable

6. We do not intend to issue a new application for the declaration of conformity associated with the declaration of conformity issued on 29 March 2024.

allowable

7. We do not intend to issue a new application for the declaration of conformity associated with the declaration of conformity issued on 29 March 2024.

allowable

8. We do not intend to issue a new application for the declaration of conformity associated with the declaration of conformity issued on 29 March 2024.

allowable

9. We do not intend to issue a new application for the declaration of conformity associated with the declaration of conformity issued on 29 March 2024.

allowable

10. We do not intend to issue a new application for the declaration of conformity associated with the declaration of conformity issued on 29 March 2024.

allowable

11. We do not intend to issue a new application for the declaration of conformity associated with the declaration of conformity issued on 29 March 2024.

allowable

12. We do not intend to issue a new application for the declaration of conformity associated with the declaration of conformity issued on 29 March 2024.

allowable

13. We do not intend to issue a new application for the declaration of conformity associated with the declaration of conformity issued on 29 March 2024.

allowable

14. We do not intend to issue a new application for the declaration of conformity associated with the declaration of conformity issued on 29 March 2024.

allowable

15. We do not intend to issue a new application for the declaration of conformity associated with the declaration of conformity issued on 29 March 2024.

allowable

16. We do not intend to issue a new application for the declaration of conformity associated with the declaration of conformity issued on 29 March 2024.

allowable

17. We do not intend to issue a new application for the declaration of conformity associated with the declaration of conformity issued on 29 March 2024.

allowable

18. We do not intend to issue a new application for the declaration of conformity associated with the declaration of conformity issued on 29 March 2024.

allowable

19. We do not intend to issue a new application for the declaration of conformity associated with the declaration of conformity issued on 29 March 2024.

allowable

20. We do not intend to issue a new application for the declaration of conformity associated with the declaration of conformity issued on 29 March 2024.

allowable

21. We do not intend to issue a new application for the declaration of conformity associated with the declaration of conformity issued on 29 March 2024.

allowable

Manufacturer's Declaration

Unclassified devices

In case of devices for which the conformity assessment procedure pursuant to Article 33(2) does not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 20 May 2013, the manufacturer shall declare:

1. The device complies with the essential requirements and other relevant harmonized standards.

2. The declaration of conformity is based on the following documents:

a) Declaration of Conformity (DoC) issued by the manufacturer;

b) Declaration of Conformity (DoC) issued by the Notified Body;

c) Declaration of Conformity (DoC) issued by the Economic Operator;

d) Declaration of Conformity (DoC) issued by the Authorised Representative;

e) Declaration of Conformity (DoC) issued by the Notified Body or Economic Operator.

3. The declaration of conformity is issued in accordance with the following document:

a) Declaration of Conformity (DoC) issued by the Notified Body;

b) Declaration of Conformity (DoC) issued by the Economic Operator;

c) Declaration of Conformity (DoC) issued by the Authorised Representative;

d) Declaration of Conformity (DoC) issued by the Notified Body or Economic Operator.

4. The declaration of conformity is issued in accordance with the following document:

a) Declaration of Conformity (DoC) issued by the Notified Body;

b) Declaration of Conformity (DoC) issued by the Economic Operator;

c) Declaration of Conformity (DoC) issued by the Authorised Representative;

d) Declaration of Conformity (DoC) issued by the Notified Body or Economic Operator.

5. The declaration of conformity is issued in accordance with the following document:

a) Declaration of Conformity (DoC) issued by the Notified Body;

b) Declaration of Conformity (DoC) issued by the Economic Operator;

c) Declaration of Conformity (DoC) issued by the Authorised Representative;

d) Declaration of Conformity (DoC) issued by the Notified Body or Economic Operator.

6. The declaration of conformity is issued in accordance with the following document:

a) Declaration of Conformity (DoC) issued by the Notified Body;

b) Declaration of Conformity (DoC) issued by the Economic Operator;

c) Declaration of Conformity (DoC) issued by the Authorised Representative;

d) Declaration of Conformity (DoC) issued by the Notified Body or Economic Operator.

Bratislava, 20.05.2013 - 04.01

Svetozár Šimko

Manager of Quality Management System

Signature: 

