STATEMENT

To whom it may concern,
Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU)2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

Our company has confirmed the following in accordance with the regulation EU 2023/607，

- The expiration date of our company's CE certificate (please see ANNEX I) is 2023-05-01, which will expire after the effective date of Regulation EU 2023/607 on March 2023. and
- We has made a formal application to TUV SUD under Section 4.3, first subparagraph of Annex VII of MDR, which has been confirmed by the Agency. (Please see Annex II)
- The devices covered by the formal application and the written agreement mentioned above are identified in annex III.
- The above NB will continue to monitor and audit products covered by the MDD certificate in accordance with regulatory requirements.

In accordance with all applicable provisions set out in Regulation EU 2023/607, we have satisfied the relevant requirements for the automatic renewal of the certificate validity of MDD and therefore we believe that the conformity of the products contained in the annexes to this Declaration can be satisfied on an ongoing basis.

Shenzhen JCR Medical Technology Limited Company

2023-06-09

Business Stream Products
Certification Department

TÜVRheinland®
Precisely Right.

TÜV Rheinland LGA Products GmbH • 51105 Köln

Shenzhen JCR Medical Technology
Limited Company
101, Building 1, Plant B, No.1,
Tianfu Road, Tianliao Community,
Yutang Street, Guangming District,
Shenzhen
518132 Guangdong
P.R. China

Contact

Tel. +49 911 655-5225
Mail: medical-products@de.tuv.com

Date December 14, 2021

Application for : **QMS**
Certificate No. : HD 60147227 0001
Requirement : Richtlinie 93/42/EWG
Confirmation letter ID : 2020-05-21_ HD 60147227 0001

Report no. : 10919665-100

Dear Madame or Sir,

Update of information to Certificate no. HD 60147227 0001, issued on 03.12.2021

The change notification received on 10.10.2021 related to the information stipulated on the above mentioned certificate was assessed and information confirmed.
We confirm that the change notification is not considered a significant change in design or intended purpose under Regulation (EU) 2017/745 on medical devices (MDR), Article 120(3).

With this document we would like to confirm the following updated information to the afore mentioned certificate

Revised Manufacturer name

Old Manufacturer name:	Shenzhen JCR Technology Limited Company
New Manufacturer name:	Shenzhen JCR Medical Technology Limited Company

Best regards,

Dipl.-Ing. W. Hsu

Certification body

MS-0045446 rev. 0

TÜV Rheinland
LGA Products GmbH

Am Grauen Stein
51105 Köln
Germany

Headquarter

Tillystraße 2
90431 Nuremberg

Phone. +49 911 655 5225
Fax +49 911 655 5226
service@de.tuv.com
www.tuv.com/safety

EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

TÜVRheinland®

Registration No.: HD 60147227 0001

Report No.: 17063018 007

Manufacturer:

Shenzhen JCR Technology
Limited Company
101, Building 1, Plant B, No. 1, Tianfu
Road, Tianliao Community, Yutang Street
Guangming District
Shenzhen, Guangdong
518132 Guangdong
P.R. China

Products:

Disposable Pressure Transducers

Replaces Approval, Registration No.: DD 60127887 0001

Expiry Date: 2023-05-01

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2020-05-21

Date: 2020-05-21

Notified Body

Wenxiang Zhang

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle III

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

To Whom It May Concern

LETTER OF DECLARATION

This letter is to declare that the extension of validity of JCR disposable pressure transducers CE Certificate: IT2077124_Request Shenzhen JCR Medical Technology Limited Company, application of article 97 MDR (reference number - ShenzDPT220323)

Sincerely,

Shenzhen JCR Medical Technology Limited Company

PROCEDURE: MDR ARTICLE 97 (1) REQUEST FOR A MEDICAL DEVICE/ ACTIVE IMPLANTABLE MEDICAL DEVICE

You received this document because you would like to apply for the procedure regarding article 97 (1) of the MDR for legacy devices for which the MDD or AIMDD certificate[1] expires before the issuance of a MDR certificate, in conjunction with MDCG 2022-18. We request that you take note of the procedure below.

MDR Article 97(1) Market surveillance – Other non-compliance
TERMS AND CONDITIONS

In December 2022 the MDCG Position Paper on the application of Article 97 (1) MDR to legacy devices for which the MDD or AIMDD certificate expires before the issuance of a MDR certificate (hereafter: MDCG 2022-18). As delineated in MDCG 2022-18, the competent authority (CA) of a member state can, in accordance with Article 94 MDR, carry out an evaluation of devices suspected of presenting an unacceptable risk or other non-compliance.

Article 97 (1) of the MDR enables CAs to require a manufacturer, or its authorised representative to bring a non-compliance to an end within a reasonable and clearly defined period, with the effect that the devices continue to be placed on the EU-market. The non-conformity concerns an MDD/AIMDD certificate of the devices that has expired or expires before the issuance of the required certificate in accordance with the MDR. Specific conditions apply: the conformity assessment by the Notified Body and the certification of devices according to the MDR will not be finalised before the MDD or AIMDD certificate expires, and the device does not present an unacceptable risk to health and safety of patients or the public health. These conditions will ensure that the conformity of the devices concerned is established as soon as possible under the conditions set by the CA, while limiting as much as possible the impact on the supply of safe and effective devices to patients and healthcare providers.

The application of Article 97 (1) MDR is always temporary and the period by when the manufacturer should bring the device into compliance will be proportionate to the extent/severity of the non-compliance in accordance with Article 97(1) MDR read in conjunction with MDCG 2022-18.

Article 97 (1) in conjunction with MDCG 2022-18 **only applies** to the following conditions listed in MDCG 2022-18: Please check whether these conditions are applicable before you (manufacturer or authorised representative) submit your application.

☑ Your legal base as a manufacturer or Authorised Representative is situated in the Netherlands.
☑ The MDD/AIMDD certificate of the devices has expired or expires before the issuance of the required certificate in accordance with the MDR.
☑ Devices fall under the scope of Article 120(3) MDR after 26 May 2021 (DOA of the MDR); considered legacy devices[2];
☐ Devices are 'in transition' from the MDD/ AIMDD to the MDR; **OR**
☑ Devices for which despite reasonable efforts undertaken by the manufacturer to obtain certification under the MDR, the relevant conformity assessment procedure involving a notified body has not been concluded in time.

Article 97(1) in conjunction with MDCG 2022-18 does **not** apply to:
- devices for which the certificate issued under the MDD or AIMDD has been suspended or withdrawn by the notified body. The Directive's certificate must have been or must be valid at the date of its expiry.
- devices that have undergone a significant change in design or intended purpose after 26 May 2021 within the meaning of Article 120(3) MDR as further explained in MDCG 2020-3.

[1] In this document, the word certificate should be understood as certificate or certificates
[2] Legacy Devices, Article 120 paragraph 3 (MDCG 2021-25) Devices placed on the market after DoA MDR (May 26, 2021) until May 26, 2024 under the following conditions:
- class I MH Directive 93/42/EEC (MDD), with an EC declaration of conformity drawn up before 26 May 2021 and who must go through a conformity assessment procedure under the MDR at a notified body under the MDR;
- devices with a valid CE certificate for Directive 90/385/EEC (AIMDD) or 93/42/EEC (MDD) before 26 May 2021. It concerns a valid certificate at the time of expiry, which has not been revoked or suspended.

SUBMITTING YOUR APPLICATION:

If you declare that your devices meet the criteria mentioned above, you must complete and submit this form and provide the following statements, that apply to **each medical device** on the application. Subsequently send the completed form, annex I, containing a list of all applicable medical devices, and the documentation in points A to C to the CIBG via: CIBGartikel97@minvws.nl.

Please attach your documentation to the e-mail with in the subject line: "Article 97 application request + name manufacturer". The Competent Authority (IGJ) will subsequently assess the content of your request. After the assessment of your application, the IGJ will draw up a formal decision.

Please provide the following information:

1. Information to be provided in this table by the applicant:

If the Applicant is a **Manufacturer** based in the Netherlands:	
• Company name of legal entity:	
• Address of legal entity:	
• Single Registration Number (SRN):	
• Name, function and contact details of responsible executive who signs the application letter:	
• Name, function and contact details of the contact person for this application:	
If the applicant is an **Authorised Representative** based in the Netherlands:	
• Company name of legal entity:	Lotus NL B.V.
• Address of legal entity:	Koningin Julianaplein 10, 1e Verd, The Hague, Netherlands
• Single Registration Number (SRN):	NL-AR-000000121
• Name, function and contact details of responsible executive who signs the application letter:	Peter, Manager, peter@lotusnl.com
• Name, function and contact details of the contact person:	Peter, Manager, peter@lotusnl.com
• Name of legal manufacturer of the medical devices for which the application is submitted:	Shenzhen JCR Medical Technology Limited Company
• Name, function and contact details of a contact person for the manufacturer:	Shuhong Guo, Management representative, +8613760251305
If the applicant is an **Manufacturer** based outside the EU:	
• Company name of legal entity:	
• Address of legal entity:	
• Single Registration Number (SRN):	
• Name, function and contact details of responsible executive who signs the application letter:	
• Name, function and contact details of the contact person:	
• Name of the Authorised Representative based in the Netherlands:	
• Name, function and contact details of a contact person for the Authorised Representative:	

2. Please provide a list of medical devices for which the application is made. Provide this list in **tabulated form** as **Annex 1** to your application. In Annex I you should provide the following basic information for **each** medical device:

For every medical device:	
• Commercial name/trade name:	Disposable Pressure Transducer
• Type of device:	single Use
• GMDN/EMDN code:	EMDN CODE : Z1203020301
• Unique identification by UDI-DI or MD nomenclature code classification according to MDD or AIMDD:	basic UDI-di: 6972306330000000005AC MDD classification: IIb
• Classification according to MDR:	IIb
• Notified Body name:	TÜV Rheinland LGA Products GmbH
• Notified body identification number MDD/AIMDD certificate:	CE 0197
• Identification number of MDD/AIMDD certificate under which it was marketed under the MDD/AIMD:	HD 60147227 0001
• Expiry date of MDD/AIMDD certificate under which it was placed on the market:	01-05-2023
• The date from which the device is not or will not be in compliance with MDR:	01-05-2023
• The reason the device is not or will not be in compliance with MDR:	The product has applied to the notified body for MDR conformity assessment, but it has not yet been completed.

DOCUMENTATION TO SUBMIT WITH YOUR REQUEST

A. Most recent notified body's audit report, with regard to information about potential safety-related shortcomings identified by the relevant notified body during the last surveillance audit, and confirmation regarding satisfactory resolution; or the absence thereof. The certificate and devices to which the audit report applies must be clearly identified.
B. Most recent report or PSUR by manufacturer containing all relevant data gathered through its post-market surveillance (PMS) system, in particular data concerning incidents, serious incidents and/or field safety corrective actions, or the absence thereof. The certificate and devices to which the report or PSUR applies must be clearly identified. • If no such report is yet available (i.e., for Class I and Class IIa devices), a statement of the manufacturer that no incidents, serious incidents and/or field safety corrective actions have been observed with the medical device concerned from analysis of available PMS data.
C. The most recent CE-certificate issued by a notified body in accordance with MDD or AIMDD (not suspended nor withdrawn).

STATEMENTS

You submit a request under the provisions of Article 97(1), first paragraph of Regulation (EU) 2017/745
Thereby you declare[3] that (please tick all applicable boxes):

2	Statements to be provided by applicant. **For each medical device and for each certificate concerned**, the applicant and/or manufacturer declares that:
☑	The CE-certificate covering the medical device concerned was issued by a notified body in accordance with MDD or AIMDD and is (or was) valid at the expiry date of that certificate (not suspended nor withdrawn).
☑	The device is (or was) at the time of expiry of the MDD/AIMDD certificate a 'legacy device' within the meaning of MDCG 2021-25[4].
☐	*If the device is NOT (or was NOT) at the time of expiry of the MDD/AIMDD certificate a 'legacy device' within the meaning of MDCG 2021-25[5].* the manufacturer qualifies as SME considering the definition given in https://single-market-economy.ec.europa.eu/smes/sme-definition_en. AND that the notified body was not designated for the MDR in time and/or that it cannot process the application before the expiry date of the directive certificate due solely to limited capacity. OR that reasonable and appropriate attempts were undertaken to obtain certification by notified bodies, appropriately designated for the medical devices in question, in a timely manner; and these notified bodies cannot process the application before the expiry date of the directive certificate due solely to limited capacity.
☑	The device is not or will not be in compliance with the MDR before expiry of the MDD/AIMDD certificate, and that the applicant formally requests the Competent Authority of the Netherlands to perform an evaluation of the device concerned as described in MDR art. 94. Applicant also requests the Competent Authority of the Netherlands to impose all necessary measures in accordance with MDR art. 97(1), in conjunction with MDCG 2022-18 and its current intervention policy MDR/IVDR.
☑	There is or will be no significant change(s) in design or intended purpose since 26 May 2021 and until the end of non-compliance as described in MDR art. 120 (3) and MDCG 2020-3.
☑	The applicant, the manufacturer and the medical device will comply with all applicable provisions in the MDD/AIMDD until the end of the non-compliance.
☑	The applicant, the manufacturer and the medical device will comply with all applicable provisions in the MDR, particularly with regard to PMS, vigilance and market surveillance as described in MDR art. 120 (3) and MDCG 2021-25.
☑	To the best knowledge of the applicant, there is no unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health, as evidenced by: • A valid MDR QMS certificate by a notified body; and/or a valid ISO 13485 certificate **AND**

[3] Please note that the IGJ will randomly request supporting documentation for declarations made amongst all applicants in the declarations section.

[4] Legacy device Article 120 paragraph 3 (MDCG 2021-25)
Devices placed on the market after DoA MDR (May 26, 2021) until May 26, 2024 under the following conditions:
- class I MH Directive 93/42/EEC (MDD), with an EC declaration of conformity drawn up before 26 May 2021 and who must go through a conformity assessment procedure under the MDR at a notified body under the MDR;
- devices with a valid CE certificate for Directive 90/385/EEC (AIMDD) or 93/42/EEC (MDD) before 26 May 2021.
It concerns a valid certificate at the time of expiry, which has not been revoked or suspended.

[5] Legacy device Article 120 paragraph 3 (MDCG 2021-25)
Devices placed on the market after DoA MDR (May 26, 2021) until May 26, 2024 under the following conditions:
- class I MH Directive 93/42/EEC (MDD), with an EC declaration of conformity drawn up before 26 May 2021 and who must go through a conformity assessment procedure under the MDR at a notified body under the MDR;
- devices with a valid CE certificate for Directive 90/385/EEC (AIMDD) or 93/42/EEC (MDD) before 26 May 2021.
It concerns a valid certificate at the time of expiry, which has not been revoked or suspended.

	• The most recent notified body's audit report, identified no information about potential safety-related shortcomings identified during the last surveillance audit, and/or confirmed satisfactory resolution thereof. • The most recent report or PSUR by manufacturer containing all relevant data gathered through its post-market surveillance (PMS) system, in particular data concerning incidents, serious incidents and/or field safety corrective actions, identified no information about potential safety-related shortcomings. • for Class I and Class IIa devices where no PSM report or PSUR is available: no incidents, serious incidents and/or field safety corrective actions have been observed with the medical device concerned from analysis of available PMS data.
☑	The applicant and/or manufacturer will proactively and without delay inform the CA about any safety-related corrective or preventive actions, serious incidents and all other new information relevant for the assessment of the health or safety of patients, users or other persons, or to other aspects of the protection of public health.
☑	The applicant and/or manufacturer will inform all known distributors and, if applicable, importers about the non-compliance and measures to end the non-compliance.
☑	The applicant and/or manufacturer will proactively and without delay inform the CA if the manufacturer decides to end the EC-conformity assessment procedure with the Notified Body.
☑	The applicant agrees to the publication of these measures on the website of the Competent Authority in order to proactively inform end-users.
☑	The applicant has not filed, at the same time, an application under MDR Article 59.1 at the competent authority.

AFTER YOUR REQUEST

After you have submitted your request, you will receive a confirmation of receipt and reference number from the CIBG.

The CIBG and the IGJ aim to complete the processing of your application in a timely manner. The time required for this depends, among other things, on the completeness of your application and the time required to obtain additional information about your application. Only applications that are fully complete, including all required documentation, and all appropriate statements made by the applicant, will be taken into consideration.

We would like to bring to your attention that the final decision on your Article 97(1) application will be in the English language.

WITHDRAWAL OF YOUR APPLICATION

If you, as an applicant, do not wish to proceed with your request for Article 97(1), you can send a request to withdraw the application to the CIBG via: CIBGartikel97@minvws.nl.

If no documentation is provided, we trust that you do not wish to proceed with the application, and we consider this request as not submitted.

Please note that the IGJ will randomly request supporting documentation for declarations made amongst all applicants in the declarations section. The IGJ expects that the requester/manufacturer will always have this documentation available and can provide it instantly when requested by the competent authority.

You have read this document and completed it truthfully.

Name and signature: Peter

Final decision on Article 97 needs to be sent to:

Name applicant: Peter
E-mail address: peter@lotusnl.com
Address (street), house number, postal code: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
Country applicant: Netherlands.
Company and Function applicant: Lotus NL B.V. Authorised Representative
Submission date: 20-03-2023

Inspectie Gezondheidszorg en Jeugd
Ministerie van Volksgezondheid, Welzijn en Sport

> Retouradres Postbus 2518 6401 DA Heerlen

Stadsplateau 1
3521 AZ Utrecht
Postbus 2518
6401 DA Heerlen
T 088 120 50 00
F 088 120 50 01
www.igj.nl

Inlichtingen bij
P.Gayral
meldpunt@igj.nl

Ons kenmerk
2023-2866323/IGJ

Bijlagen
-

Datum 19 april 2023
Onderwerp aanvraag toepassing artikel 97 MDR

Geachte heer, mevrouw,

U heeft per e-mail een aanvraag ingediend bij het CIBG voor de toepassing van artikel 97 van de Verordening betreffende medische hulpmiddelen (EU) 2017/745 (hierna: MDR) op basis van Medical Device Coordination Group (hierna: MDCG) position paper MDCG 2022-18 (hierna: 'MDCG 2022-18').

Verzoek om reactie
Op basis van de in deze brief verstrekte informatie verzoekt de inspectie u zorgvuldig na te gaan of u nog belang heeft bij uw ingediende aanvraag. Als u geen belang meer heeft bij uw ingediende aanvraag vragen wij u om uw aanvraag voor de toepassing van artikel 97 MDR in te trekken waarna de aanvraagprocedure wordt afgesloten. U kunt uw aanvraag eenvoudig intrekken door een antwoord op deze brief te sturen naar het e-mailadres meldpunt@igj.nl waarin u aangeeft dat u uw aanvraag, onder vermelding van het aanvraagnummer, intrekt.

Als u van mening bent dat u nog steeds een goedkeuringsbesluit voor de toepassing artikel 97, lid 1 MDR nodig heeft, verzoeken wij u dit gemotiveerd in uw reactie aan ons te laten weten.

Wij vragen u om binnen 14 dagen na de verzenddatum van deze brief te reageren.

MDCG 2022-18
In de MDCG 2022-18 wordt uitgelegd hoe bevoegde autoriteiten artikel 97 MDR kunnen toepassen. Het beschrijft ook de situaties waarbij medische hulpmiddelen niet voldoen aan de MDR omdat het certificaat dat is afgegeven op grond van Richtlijn 93/42/EEG (MDD) of Richtlijn 90/385/EEG (AIMDD) is verlopen of verloopt vóór uitgifte van de benodigde certificaten onder de MDR. Door de toepassing van artikel 97 MDR in deze situaties kunnen deze medische

hulpmiddelen (zgn. 'legacy devices') nog tijdelijk op de EU-markt in de handel gebracht of in gebruik genomen worden.

Aanpassing wetgeving per 20 maart 2023

Aan deze tijdelijke situatie, beschreven in de vorige alinea, is inmiddels een einde gekomen. Op 20 maart 2023 werd namelijk de Verordening 2023/607 tot wijziging van de Verordeningen (EU) 2017/745 en (EU) 2017/746 (EU) 2023/607 gepubliceerd en is deze in werking getreden. Door aanpassing van het overgangsrecht van de MDR en IVDR wordt de geldigheidsduur van een certificaat van rechtswege verlengd of herleeft een verlopen certificaat van rechtswege mits er aan de wettelijke voorwaarden wordt voldaan. Voor het in de handel brengen of in gebruik nemen van medische hulpmiddelen tijdens de verlengde termijnen gelden aanvullende voorwaarden. Hierna schetsen wij het overgangsrecht op hoofdlijnen.

Certificaten die zijn vervallen vóór 20 maart 2023

Indien uw aanvraag ziet op certificaten die:

a. door aangemelde instanties overeenkomstig de (AI)MDD zijn afgegeven vanaf 25 mei 2017;
b. nog geldig waren op 26 mei 2021;
c. en die vóór 20 maart 2023 zijn vervallen;

dan worden deze certificaten geacht geldig te zijn tot 31 december 2027 of 31 december 2028, afhankelijk van de klasse van het medisch hulpmiddel (artikel 120, lid 3 bis MDR) *mits*
de fabrikant vóór de vervaldatum van het certificaat/de certificaten een schriftelijke overeenkomst met een aangemelde instantie heeft ondertekend voor het uitvoeren van een conformiteitsbeoordeling met betrekking tot het hulpmiddel waarop het vervallen certificaat betrekking heeft of met betrekking tot een hulpmiddel dat bedoeld is om dat hulpmiddel te vervangen. De overeenkomst betreft een overeenkomst als bedoeld in punt 4.3, tweede alinea van Bijlage VII van de MDR (artikel 120, tweede lid, tweede alinea, tweede volzin en onderdeel a MDR).

Een dergelijke overeenkomst moet:

1. schriftelijk zijn;
2. door de fabrikant en de aangemelde instantie ondertekend zijn;
3. duidelijke voorwaarden en verplichtingen bevatten zodat de aangemelde instantie overeenkomstig de MDR kan handelen;
4. de verplichting bevatten dat de fabrikant de aangemelde instantie moet informeren over vigilantieverslagen;
5. het recht van de aangemelde instantie bevatten om afgegeven certificaten te schorsen, te beperken of in te trekken;

6. de plicht van de aangemelde instantie bevatten om haar informatieverplichtingen te vervullen.

In de handel brengen of in gebruik nemen
Als aan voornoemde voorwaarden voldaan wordt herleeft de geldigheid van een verlopen certificaat van rechtswege. Om het hulpmiddel waarop het certificaat betrekking heeft ook in de handel te mogen brengen of in gebruik te nemen moet (ook) aan de volgende voorwaarden voldaan worden (artikel 120, lid 3 en artikel 120 lid 3 quater MDR):

1. de hulpmiddelen blijven voldoen aan de MDD;
2. er zijn geen significante wijzigingen in het ontwerp en het beoogde doeleind. Wat onder significante wijzigingen wordt verstaan is uitgelegd in document MDCG 2020-3;
3. de hulpmiddelen vormen geen onaanvaardbaar risico voor de gezondheid of de veiligheid van patiënten, gebruikers of andere personen, of voor andere aspecten van de bescherming van de volksgezondheid;
4. de fabrikant heeft uiterlijk op 26 mei 2024 een kwaliteitsmanagementsysteem overeenkomstig artikel 10, lid 9 MDR ingevoerd;
5. de fabrikant of gemachtigde heeft uiterlijk op 26 mei 2024 een aanvraag ingediend voor een conformiteitsbeoordeling voor het hulpmiddel waarop het certificaat met verlengde geldigheid betrekking heeft (of voor een hulpmiddel dat bedoeld is om dat hulpmiddel te vervangen). De aanvraag betreft een aanvraag zoals bedoeld in punt 4.3, eerste alinea van Bijlage VII van de MDR;
6. de fabrikant en de aangemelde instantie hebben uiterlijk op 26 september 2024 een schriftelijke overeenkomst ondertekend voor het uitvoeren van een conformiteitsbeoordeling met betrekking tot het hulpmiddel waarop het certificaat met verlengde geldigheidsduur betrekking heeft of met betrekking tot een hulpmiddel dat bedoeld is om dat hulpmiddel te vervangen. De overeenkomst betreft een overeenkomst als bedoeld in punt 4.3, tweede alinea van Bijlage VII van de MDR. De eisen die aan deze overeenkomst worden gesteld zijn bovenaan deze pagina beschreven.

Certificaten die vervallen vanaf 20 maart 2023

Indien uw aanvraag ziet op certificaten die:

a. door aangemelde instanties overeenkomstig de (AI)MDD zijn afgegeven vanaf 25 mei 2017;
b. nog geldig waren op 26 mei 2021;
c. en die daarna niet zijn ingetrokken;

dan blijven deze certificaten na het einde van de in het certificaat vermelde periode geldig tot 31 december 2027 of 31 december 2028, afhankelijk van de

klasse van het medisch hulpmiddel (artikel 120, tweede lid, tweede alinea, eerste volzin en artikel 120, lid 3 bis MDR).

In de handel brengen of in gebruik nemen
Als het bovenstaande van toepassing is wordt de geldigheid van het certificaat van rechtswege verlengd. Om het hulpmiddel waarop het certificaat betrekking heeft ook in de handel te mogen brengen of in gebruik te nemen moet (ook) aan de volgende voorwaarden worden voldaan (artikel 120, lid 3 en artikel 120 lid 3 quater MDR):

1. de hulpmiddelen blijven voldoen aan de MDD;
2. er zijn geen significante wijzigingen in het ontwerp en het beoogde doeleind. Wat onder significante wijzigingen wordt verstaan is uitgelegd in document MDCG 2020-3;
3. de hulpmiddelen vormen geen onaanvaardbaar risico voor de gezondheid of de veiligheid van patiënten, gebruikers of andere personen, of voor andere aspecten van de bescherming van de volksgezondheid;
4. de fabrikant heeft uiterlijk op 26 mei 2024 een kwaliteitsmanagementsysteem overeenkomstig artikel 10, lid 9 MDR ingevoerd;
5. de fabrikant of gemachtigde heeft uiterlijk op 26 mei 2024 een aanvraag ingediend voor een conformiteitsbeoordeling voor het hulpmiddel waarop het certificaat met verlengde geldigheid betrekking heeft (of voor een hulpmiddel dat bedoeld is om dat hulpmiddel te vervangen). De aanvraag betreft een aanvraag zoals bedoeld in punt 4.3, eerste alinea van Bijlage VII van de MDR;
6. de fabrikant en de aangemelde instantie hebben uiterlijk op 26 september 2024 een schriftelijke overeenkomst ondertekend voor het uitvoeren van een conformiteitsbeoordeling met betrekking tot het hulpmiddel waarop het certificaat met verlengde geldigheidsduur betrekking heeft of met betrekking tot een hulpmiddel dat bedoeld is om dat hulpmiddel te vervangen. De overeenkomst betreft een overeenkomst als bedoeld in punt 4.3, tweede alinea van Bijlage VII van de MDR. De eisen die aan deze overeenkomst worden gesteld zijn bovenaan pagina 2 beschreven.

Verlenging beslistermijn
De beslistermijn op uw aanvraag eindigt 8 weken nadat u uw aanvraag heeft ingediend bij het CIBG. Wij kunnen voor het einde van deze termijn geen besluit nemen op uw aanvraag. Op grond van artikel 4:14, derde lid van de Algemene wet bestuursrecht verlengen wij daarom de beslistermijn met 6 weken.

Vragen
Mocht u nog vragen hebben, aarzel dan niet om contact met ons op te nemen. Wij zijn bereikbaar van maandag tot en met vrijdag, van 9.00 tot 17.00 uur op telefoonnummer 088 - 120 50 00. U kunt ook een e-mail sturen naar meldpunt@igj.nl.

Hoogachtend,

L. Klomp
coördinerend/specialist inspecteur

Code	Description
JIBPT-01-YP	Regular disposable pressure transducers, Single-channel,Abbott type
JIBPT-01-UT	Regular disposable pressure transducers, Single-channel,Utah type
JIBPT-01-EDW	Regular disposable pressure transducers, Single-channel,Edward type
JIBPT-01-MD	Regular disposable pressure transducers, Single-channel,Medex type
JIBPT-01-BD	Regular disposable pressure transducers, Single-channel,BD type
JIBPT-01-BL	Regular disposable pressure transducers, Single-channel,Bbraun type
JIBPT-01-PVB	Regular disposable pressure transducers, Single-channel,PVB type
JIBPT-01-USB	Regular disposable pressure transducers, Single-channel,USB type
JIBPT-01-MR	Regular disposable pressure transducers, Single-channel,Mindray type
JIBPT-E-01-YP	E&type disposable pressure transducers, Single-channel,Abbott type
JIBPT-E-01-UT	E&type disposable pressure transducers, Single-channel,Utah type
JIBPT-E-01-EDW	E&type disposable pressure transducers, Single-channel,Edward type
JIBPT-E-01-MD	E&type disposable pressure transducers, Single-channel,Medex type
JIBPT-E-01-BD	E&type disposable pressure transducers, Single-channel,BD type
JIBPT-E-01-BL	E&type disposable pressure transducers, Single-channel,Bbraun type
JIBPT-E-01-PVB	E&type disposable pressure transducers, Single-channel,PVB type
JIBPT-E-01-USB	E&type disposable pressure transducers, Single-channel,USB type
JIBPT-E-01-MR	E&type disposable pressure transducers, Single-channel,Mindray type