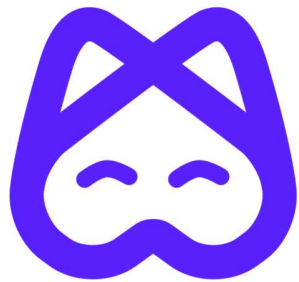


Diagnocat User Manual Version 1



Diagnocat


USER MANUAL

Version 1, dated 06.06.2022

Software version 3.1

Obsolete

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	Please read, understand, and follow all safety information contained in these instructions prior to using Diagnocat. It is recommended to retain these instructions for future reference.
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1. INTRODUCTION

1.1. ABOUT THE MANUAL

This manual is a part of a medical product – Diagnocat. Diagnocat LLC bears no liability for and provides no guarantee regarding to any damage or loss, direct or indirect, incidental or special, arising from this user manual, if performed not in compliance with it.

Prior to using the medical product, it is required to read this user manual carefully.

This user manual should be stored in a safe place for the whole duration of medical product use.

It should be provided to every subsequent owner or user of the medical product.

It should be updated on the basis of every supplementation received from the product manufacturer.






The aim of this manual is to describe a medical product – Diagnocat, taking into account the following in particular:

- Description of the medical product
- Safety of use
- Troubleshooting
- Maintenance and service

1.2. SCOPE OF VALIDITY

This user manual is valid Diagnocat in the most recent version – Diagnocat 3.1.

1.3. SYMBOLS AND MARKS USED IN THE MANUAL AND IN THE LABELING

	Manufacturer
	EU representative
	Date of manufacturing: week and year number
	Follow instructions for use
	Caution

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	Medical device
	Device complies with the European Directive on Medical Devices EU MDD 93/42/EEC

2. CHARACTERISTICS

2.1. INTENDED USE OF THE MEDICAL PRODUCT

The Diagnocat automated information system is designed for cloud-based storage and processing of digital dental images using artificial intelligence.


Diagnocat has been developed to automate the activities of dental organizations in radiological examinations, including examination uploading, screening of diagnostic images, saving, sharing, editing and drawing conclusions. Diagnocat processes files of any area of the patient's maxillofacial region.

Diagnocat is designed for use by medical professionals (dentists, orthodontists, radiologists, etc.) for education purposes and highlights anatomical areas, common conditions and previous treatments.

Diagnocat automatically produces radiological reports for easier viewing and documentation of investigation for a particular patient.

Diagnocat can also be used by managers and administrators of clinics to document patient treatment history and maintain personal records.

This is a reusable, non-invasive device for image processing and documentation. The Software cannot be used to make a decision about the diagnosis, presence or absence of a disease on the basis of the online screening, without additional investigation.

	Any other application of the medical product is considered inconsistent with the intended use and has to be excluded.
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2.2. RECOMMENDATIONS FOR USING DIAGNOCAT

Diagnocat is designed to assist healthcare professionals in identifying anatomical areas, general conditions, and previous treatments during initial dental consultations, follow-up patients, control X-rays, and other situations that require examination and interpretation of digital images.

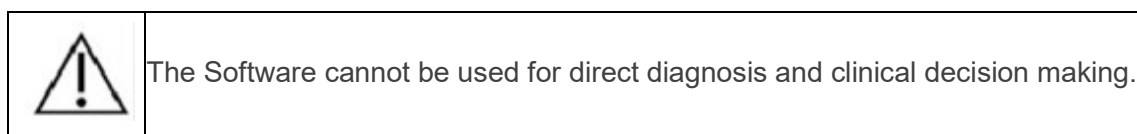
The Diagnocat library contains information about the following classes of detections:

- Anatomy of Maxillo-Facial Region
- Conditions Related to Dental Treatment
- Anomalies Related to the Teeth

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- Conditions Related to Loss of Tooth Structure
- Inflammatory Lesions of the Jaws
- Cysts and Cyst- like Lesions Involving the Jaws
- Other Diseases Affecting the Jaws
- Trauma and Fractures
- Malocclusion
- Temporomandibular Joints Disorders

2.3. CONTRAINDICATIONS



Although Diagnocat neural networks are trained on a large diverse dataset it is necessary to remember that in order for the analysis to work correctly, it is necessary to exclude studies of poor quality.

- Applying the Software to poor quality dental pictures is forbidden. (This can lead to incorrect data collection)

2.4. POTENTIAL ADVERSE EFFECTS AND SAFETY OF THE MEDICAL PRODUCT

This medical product is completely safe for use by people, provided that it is used according to the user manual.

2.5. WARNINGS, PRECAUTIONS, AND LIMITATIONS



It is forbidden to download or transmit any messages or content of any type that may disregard or violate any of the rights of any party.



It is forbidden to use this Software for any purpose in violation of local, state, national or international laws



It is forbidden to use this application as a means of advertising or other distributing of undesirable materials to the third parties



You may not use this application to publish or transmit any material that is illegal, obscene, threatening, abusive, slanderous, hateful or embarrassing to any other person or organization

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It is forbidden to try to disable, “hack” or otherwise interfere with the proper functioning of this software



Diagnocat LLC. does not give any guarantees regarding the time required for processing any request; and if you are faced with an emergency you should not seek assistance from this guide but instead should call emergency medical service immediately.



Before using Diagnocat, please make sure that the device is working properly.



Clinicians should review Diagnocat reports concurrently with original images before making a final determination on a case.



Diagnocat is an adjunct tool and does not replace the role of the clinician. Clinicians must not use the CAD generated output as the primary interpretation.



Diagnocat is not designed to detect findings other than is listed in paragraph 2.2. Clinicians should review original images for all suspected pathologies.



All radiographic images must have proper quality. Diagnocat performance may be reduced on images with poor quality.



Diagnocat should be used according to the manual.

2.6. ADDITIONAL INFORMATION

You can find more information at www.diagnocat.com

2.7. MEDICAL PRODUCT CLASSIFICATION

Diagnocat medical product has been classified according to Annex VIII to the REGULATION (EU) 2017/745 as belonging to class I and is subject to Rule 11.

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2.8. LOGO



2.9. COMPLIANCE WITH STANDARDS

The medical product meets the requirements of the IEC 62304 International Standard.

3. MEDICAL PRODUCT FUNCTIONING

3.1. TECHNICAL PARAMETERS

The medical product is constituted by software available via Web Application with the use of Chrome web browser, or through the WebAPI via HTTP REST protocol, described in the technical documentation available to the integrators or through supported applications.

The address of Web Application and WebAPI where the service is available is provided together with the software license.

Diagnocat takes advantage of a neural network architecture.

3.2. SYSTEM REQUIREMENTS:

Diagnocat software requirements:

Any operating system capable of running required Google Chrome version.

Browser: Google Chrome 75+ and should be updated.

Diagnocat hardware requirements:

Minimal processor with at least 2 CPU cores

2 GB RAM or more



Recommended: Processor: 4 core. Memory: 4 GB RAM.

50 Mbps or faster Ethernet interface to your institution's DICOM network



If you use a browser other than the one specified here, the results may be unpredictable

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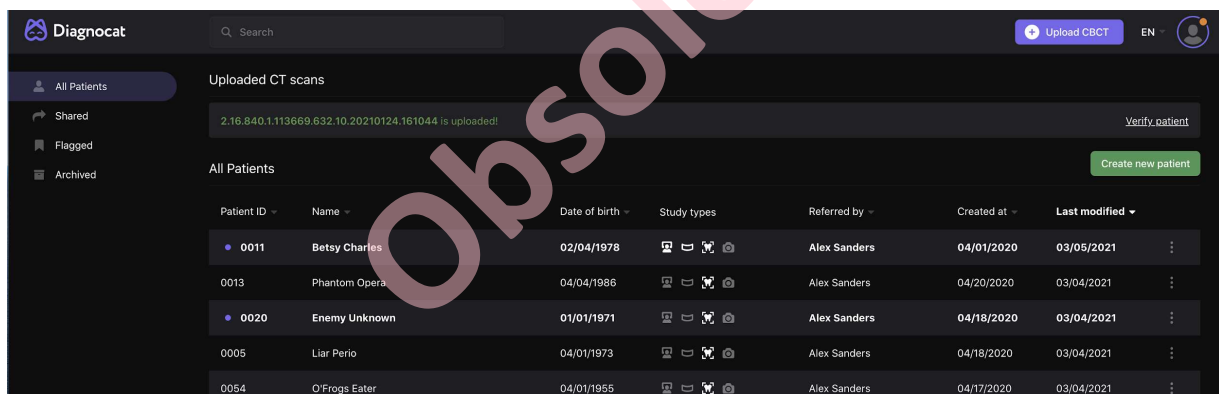
	If you use a DICOM files that do not fully conform to DICOM standard, the results may be unpredictable
	If you use a Windows system older then Windows 8, the device functionality might be disrupted

3.3. MODE OF OPERATION

Diagnocat is a cloud-based service. Users should upload an x-ray image and order an analysis. System will run a collection of Machine Learning models in the background in order to produce the requested analysis. After that the User will browse the analysis results in the web UI, correct them if there's any machine errors, then print them and/or receive a PDF of the results.

3.4. CREATING AND MANAGING PATIENTS ACCOUNTS

Open the Diagnocat home page in your Chrome browser. It contains a list of patient accounts, a folder menu for structuring patients, and a search box.



3.5. PATIENT ACCOUNT PAGE

To create patient account press “Create new patient” on the main page.

The patient account page contains generated preview reports, patient information, and a “Study Type” menu for switching between modalities. The number in brackets in the menu indicates the number of reports on each modality page.

3.6. UPLOAD OF DIGITAL RADIOGRAPHS

The medical product analyses all types of dental digital radiographs including:

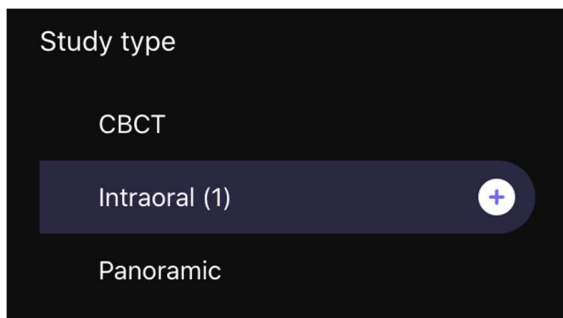
- intraoral x-rays
- panoramic x-rays

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- CBCT

Images are uploaded to Diagnocat manually by clicking “+” on the Study type menu or automatically via integration with imaging software.

The radiological data used as input for Diagnocat are 2D dental radiographs in JPEG, TIFF , PNG or DICOM format and 3D radiographs of dent-maxillo-facial area in DICOM format.



3.7. PRODUCING INTRAORAL X-RAYS RADIOLOGY REPORT

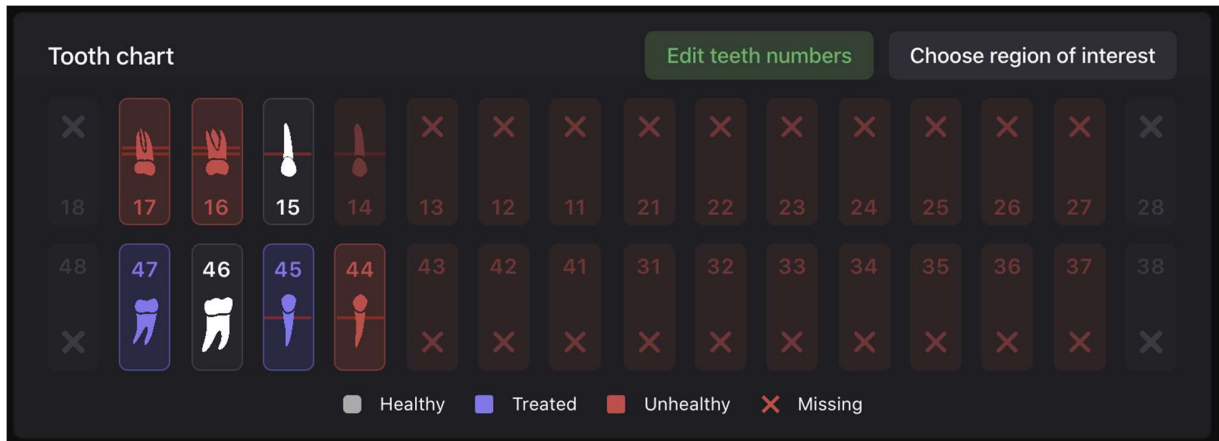
Once an intraoral x-ray image is uploaded a report is generated automatically. To open the report, click on the appeared link “Needs numbering validation” on the modality page. Check numbers of detected teeth and modify them if needed by clicking on number icons.



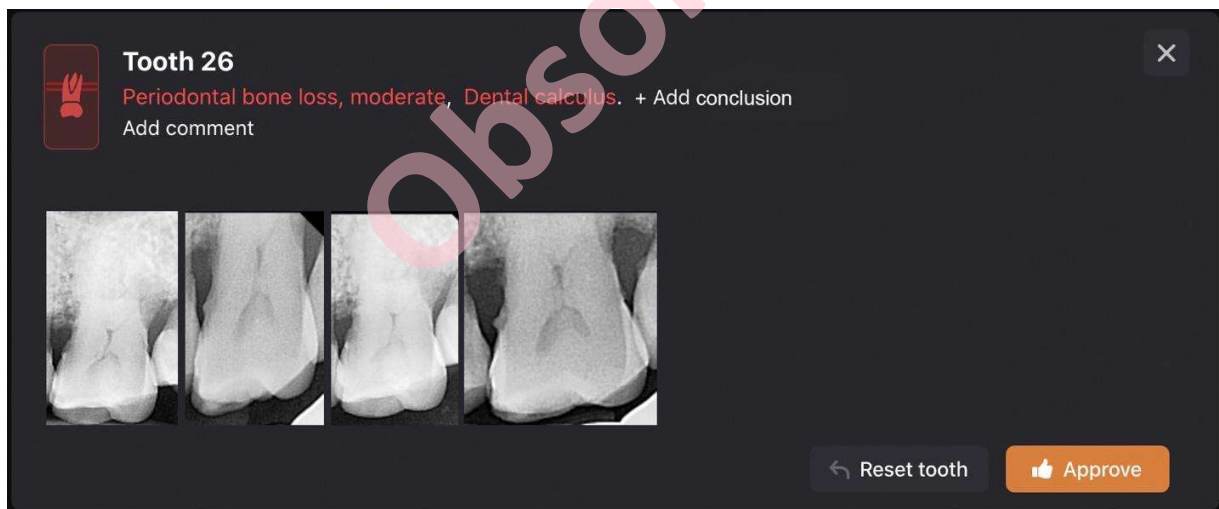
After confirmation of teeth numbers a page of the report will be opened. It contains a dental chart that is used for choosing regions of interest navigating within the report page and teeth cards with images of teeth and corresponding findings.

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Tooth chart also indicates the state of detected teeth by color coding.



Tooth cards are the tool for radiological description of individual teeth. They are prefilled with Diagnocat screening. Hover your mouse over findings and a bounding box will appear around an associated condition on the image. Modify or add findings by clicking on text. Approve when finished.



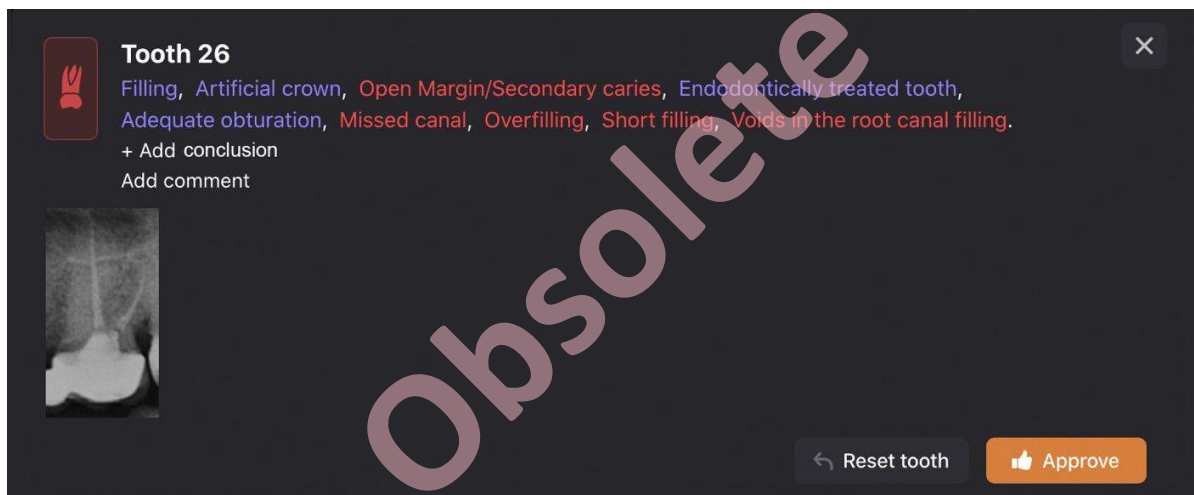
3.8. PRODUCING PANORAMIC X-RAYS RADIOLOGY REPORT

Use the same algorithm for uploading and generating a pano report as described in the paragraph 3.5. Use of panorama menu to manage image parameters.

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Tooth cards of the panoramic report contain crops of detected teeth and associated findings for further evaluation.



3.9. PRODUCING CBCT RADIOLOGY REPORT

Use the same algorithm for uploading and generating a CBCT report as described in the paragraph 3.5.

After carrying out the analysis, the result is presented as a panoramic reconstruction of 3D volume.

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Tooth cards contain a set of slices of a tooth.

Tooth 36

2 roots 92% , 3 canals 77% , Periodontal bone loss, mild, Filling 89% ,
Endodontically treated tooth 94% , Missed canal 71% , Short filling 98% ,
Voids in the root canal filling 91% . + Add conclusion

Add comment

Axial Axial Axial Sagittal Frontal Frontal

Reset tooth All slices Approve

To change or add slices press “All slices” and select the ones you are interested in from the appeared window.

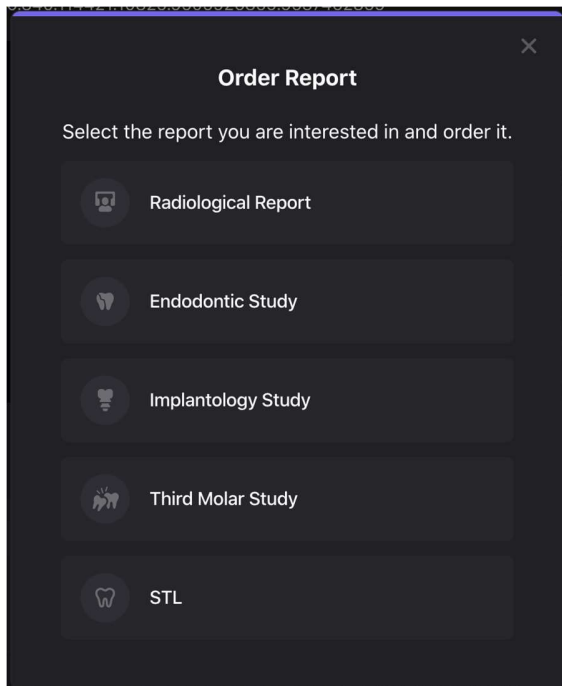
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3.10. OTHER TYPES OF CBCT REPORTS

CBCT modality allows you to generate different types of reports tailored to your clinical needs. Press “Order report” and choose report type in the appeared window. To produce reports containing sets of slices of the area of interest choose Endodontic, Implantology or Third molar report. To export DICOM to STL format for further downloading press STL button.

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3.11. DESIGNING RADIOLOGY REPORT

After the report is ready the user can customize the printed form of the radiological report:

- -invert images
- show or hide basic elements
- select print type

Radiological reports can be downloaded in PDF format or sent to a printer for printing.

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Select clinic:

Dental Fantasy

Select report version:

Full

Inverted

Probabilities

Dental chart

Show upper jaw

Show lower jaw

Show diagnoses

Show slices

Referral recommendations

Orthodontic screening

Study meta info

Select print type:

Color

Black & White


Not signed by doctor

Download PDF Print

If you want the Conclusion to be displayed in printed version or PDF, it is necessary to sign the report at the previous step

Radiological Report: Teeth 17—47
02.15.2021

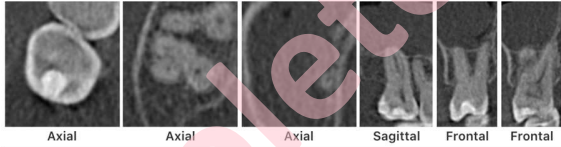
Patient name: Betsy Charles Patient ID: 0011 Age: 43
Date of birth: 02/04/1978 Scan date: 02/15/2021 Gender: Female




18	17	16	15	14	13	12	11	21	22	23	24	25	26	27	28
48	47	46	45	44	43	42	41	31	32	33	34	35	36	37	38

Healthy Treated Unhealthy Missing

Tooth 17 3 roots, 3 canals, Filling.



Tooth 16 3 roots, 4 canals, Filling.



3.12. SHARING REPORTS

To share reports with others via email press “Share” button on the patient account screen. Input email or copy a link to share. Guest users will have an access limited to the certain shared report.

Share Patient Profile

Send to email Share link

To share the patient profile, type in an email address and click the Share button

4. ACTIVITIES DURING OPERATION OF DIAGNOCAT

4.1. USING DIAGNOCAT

The description of how to use Diagnocat is included in the user manual of a supported application or in the technical documentation provided with the software.

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In order to use Diagnocat, an Internet connection is required.

The WebAPI is available via the Internet, and its address and technical documentation are provided together with the medical product license.

4.2. USER MANUAL AVAILABLE ONLINE

The most recent version of the user manual is available at the www.diagnocat.com website.

The user manual is available in the form of a PDF file. In order to read its content properly, it is recommended to use the Adobe Acrobat Reader DC software version 2019.008.20071 or newer. This software is available at the website of its producer: www.adobe.com. In order to receive a printed version of the user manual please send a request to the address of our registered seat: 129281, Moscow, proyezd Olonetskiy, 4/2, pom II, office 7A, Russian Federation. The manual will be delivered within 7 days from receiving the request.

5. TROUBLESHOOTING

In the event of encountering any problems while using Diagnocat it is necessary to:

Make sure that the inquiries sent to Diagnocat meet the requirements described in the medical product's technical documentation.

Analyse the result (error) obtained and compare it to the technical documentation.

If in spite of ensuring compliance with the technical documentation the issues keep occurring, please contact the manufacturer.

6. MAINTENANCE AND SERVICE

In case of noticing any malfunctions in the functioning of the medical product, contact the maintenance service at the e-mail address: support@diagnocat.com


6.1. PRIVACY AND SECURITY

	Please read our Privacy and Security Policy on the website www.diagnocat.com , before using the app.
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You clearly understand and accept the risk of any unapproved or intentional data disclosure, or any delay, interruption or damage of data or any other information, while data transfer. Keep you Username and Password private. Failure to do so may also compromise the confidentiality of your information.

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6.2. WARRANTY AND LEGAL NOTICE

	Please read our Warranty Information and legal notices (including the disclaimer and copyright information) on the website www.diagnocat.com , before using the app.
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6.3. FOR HELP AND ASSISTANCE

CONTACT INFORMATION

For general and product-related comments, questions, or concerns, please contact the local reseller.

MANUFACTURER

LLC "DIAGNOCAT"

21 Palekhskaya Street, Floor/Office/Room 1/II-III/13

Yaroslavl Municipal District, Moscow Intra-City Area

129337, Russian Federation

<https://www.diagnocat.com/>

Phone: +7 499 753-77-90

E-mail: support@diagnocat.com

Please report of any serious incident that has occurred in relation to the device injury or adverse event to the local competent authority and to Diagnocat LLC. Please refer to the manufacturer's website for the updated contact info: <https://www.diagnocat.com>, if necessary.

SWITZERLAND REPRESENTATIVE

Freyr Life Sciences GmbH,

Bahnhofplatz,

CH-6300 Zug,

Switzerland

Tel: +41 225083729

email: CH-REP@freyrsolutions.com

Please report of any serious incident that has occurred in relation to the device injury or adverse event to the local competent authority and to sales@diagnocat.com

Document Signatures

Participant Name	Participant Type	Action	Task Performed On
Sofia Bulgakova (Quality assurance and Regulatory affairs specialist)	Owner	Review Not Required	2022-08-12 07:41 GMT
Sofia Bulgakova (Quality assurance and Regulatory affairs specialist)	Approver	Approve Document	2022-08-12 07:42 GMT

Revision History

Version	Effective Date	Prepared by	Summary of Changes/Justifications
1.0	2022-08-22	Sofia Bulgakova	Initial Version

Obsolete