

Date

16 December 2025

Our reference

2023-225390

Contact

070 8888 500

Subject**Decision approving Processor Binding Corporate Rules of Illumina**

The Autoriteit Persoonsgegevens,

Pursuant to the request by **Illumina Netherlands B.V.**, on behalf of the group **Illumina, Inc.**, (hereinafter '**Illumina**'), received on **22-02-2022**, reference **2023-225390**, formerly z2022-04408, for approval of their binding corporate rules for processor;

Having regard to Articles 47, 57 and 64 of the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation or GDPR);

Having regard to the judgment of the Court of Justice of the European Union in Data Protection Commissioner v. Facebook Ireland Ltd and Maximillian Schrems, C-311/18 of 16 July 2020;

Having regard to EDPB Recommendations 01/2020 on measures that supplement transfer tools to ensure compliance with the EU level of protection of personal data of 18 June 2021;

Makes the following observations:

1. Article 47(1) of the EU General Data Protection Regulation 2016/679 (GDPR) provides that the Autoriteit Persoonsgegevens shall approve Binding Corporate Rules (BCRs) provided that they meet the requirements set out under this Article.
2. The implementation and adoption of BCRs by a group of undertakings is intended to provide guarantees to controllers and processors established in the EU as to the protection of personal data that apply uniformly in all third countries and, consequently, independently of the level of protection guaranteed in each third country.

3. Before carrying out any transfer of personal data on the basis of the BCRs to one of the members of the group, it is the responsibility of any data exporter in a Member State, if needed with the help of the data importer, to assess whether the level of protection required by EU law is respected in the third country of destination in the case of the specific data transfer, including onward transfer situations. This assessment has to be conducted in order to determine whether any legislation or practices of the third country applicable to the to-be-transferred data may impinge on the data importer's and/or the data exporter's ability to comply with their commitments taken in the BCRs, taking into account the circumstances surrounding the transfer. In case of such possible impingement, the data exporter in a Member State, if needed with the help of the data importer, should assess whether it can provide supplementary measures in order to exclude such impingement and therefore to nevertheless ensure, for the envisaged transfer at hand, an essentially equivalent level of protection as provided in the EU. Deploying such supplementary measures is the responsibility of the data exporter and remains its responsibility even after approval of the BCRs by the competent supervisory authority (SA) and, as such, they are not assessed by the competent SA as part of the approval process of the BCRs.
4. In any case, where the data exporter in a Member State is not able to implement supplementary measures necessary to ensure an essentially equivalent level of protection as provided in the EU, personal data cannot be lawfully transferred to a third country under these BCRs. In the same vein, where the data exporter is made aware of any changes in the relevant third country legislation that undermine the level of data protection required by EU law, the data exporter is required to suspend or end the transfer of personal data at stake to the concerned third countries.
5. In accordance with the cooperation procedure as set out in the Working Document WP263 rev.01¹, the Processor BCRs application of **Illumina** was reviewed by the Autoriteit Persoonsgegevens, as the competent SA for the BCRs (BCR Lead) and by two SAs acting as co-reviewers, *in this case the Romanian and Italian SAs*. The application was also reviewed by the concerned SAs to which the BCRs were communicated as part of the cooperation procedure.
6. The review concluded that the Processor BCRs of **Illumina** comply with the requirements set out by Article 47(1) of the GDPR as well as the Working Document WP257 rev.01² and in particular that the aforementioned BCRs:

¹ Endorsed by the EDPB on 25 May 2018.

² Endorsed by the EDPB on 25 May 2018.



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- i. Are legally binding and contain a clear duty for each participating member of the group including their employees to respect the BCRs by entering in an Intra-Group Agreement (*Part 1, Section 5 of the BCRs and the Intra-Group Agreement*);
- ii. Expressly confer enforceable third-party beneficiary rights to data subjects with regard to the processing of their personal data as part of the BCRs (*Part 3 of the BCRs*);
- iii. Fulfil the requirements laid down in Article 47(2) of the GDPR:
 - a) The structure and contact details of the group of undertakings and each of its members are described in the application form WP265 that was provided as part of the file review and *Appendix 1 to the BCRs*;
 - b) the data transfers or set of transfers, including the categories of personal data, the type of processing and its purposes, the type of data subjects affected and the identification of the third country or countries in question are specified in *Appendix 2 to the BCRs*;
 - c) the legally binding nature, both internally and externally, of the Processor BCRs is recognized in *Part 1, section 5 of the BCRs*;
 - d) the application of the general data protection principles, in particular purpose limitation, data minimisation, limited storage periods, data quality, data protection by design and by default, legal basis for processing, processing of special categories of personal data, measures to ensure data security, and the requirements in respect of onward transfers to bodies not bound by the BCRs are detailed in *Part 2, Rules 1-5 of the BCRs*;
 - e) the rights of data subjects in regard to processing and the means to exercise those rights, including the right not to be subject to decisions based solely on automated processing, including profiling in accordance with Article 22 of the GDPR, the right to lodge a complaint with the competent SA and before the competent courts of the Member States in accordance with Article 79 of the GDPR, and to obtain redress and, where appropriate, compensation for a breach of the BCRs which are set forth in *Part 2, Rule 1 and 7, and Part 3 of the BCRs*;
 - f) the acceptance by the controller or processor established on the territory of a Member State of its liability for any breaches of the BCRs by any



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member concerned not established in the Union as well as the exemption from that liability, in whole or in part, only if the concerned party proves that that member is not responsible for the event giving rise to the damage are specified in *Part 3 of the BCRs*;

- g) how the information on the BCRs, in particular on the provisions referred to in points (d), (e) and (f) of Article 47(2) of the GDPR are provided to the data subjects in addition to Articles 13 and 14 of the GDPR, is specified in *Part 2, Rule 7 of the BCRs*;
- h) the tasks of any data protection officer designated in accordance with Article 37 of the GDPR or any other person or entity in charge of monitoring the compliance with the binding corporate rules within the group of undertakings, or group of enterprises engaged in a joint economic activity, as well as monitoring training and complaint-handling are detailed in *Part 4, section 1 of the BCRs*;
- i) the complaint procedures are specified in *Part 2, Rule 7 of the BCRs*;
- j) the mechanisms put in place within the group of undertakings for ensuring the monitoring of compliance with the BCRs are detailed in *Part 2, Rule 9, and Part 4, section 3 of the BCRs*.

Such mechanisms include data protection audits and methods for ensuring corrective actions to protect the rights of the data subject. The results of such monitoring are communicated to the person or the entity referred to in point (h) above and to the board of the controlling undertaking of the group of undertakings (in this situation to **illumina Inc.** headquarters, as well as to the data privacy organisation) and are available upon request to the competent SA;

- k) the mechanisms for reporting and recording changes to the rules and reporting those changes to the SAs are specified in *Part 4, section 4 of the BCRs*;
- l) the cooperation mechanism put in place with the SA to ensure compliance by any member of the group of undertakings is specified in *Part 2, Rule 8 of the BCRs*.

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The obligation to make available to the SA the results of the monitoring of the measures referred to in point (j) above is specified in *Part 4, section 3 of the BCRs*;

- m) the mechanisms for reporting to the competent SA any legal requirements to which a member of the group of undertakings is subject in a third country which are likely to have a substantial adverse effect on the guarantees provided by the binding corporate rules are described in *Part 2, Rule 6 of the BCRs*;
- n) finally, provide for an appropriate data protection training to personnel having permanent or regular access to personal data (*Part 4, section 2 of the BCRs*).

The EDPB provided its **Opinion 30/2025** in accordance with Article 64(1)(f) of the GDPR.

DECIDES AS FOLLOWING:

1. The Autoriteit Persoonsgegevens approves the Processor BCRs of **Illumina** as providing appropriate safeguards for the transfer of personal data in accordance with Article 46(1) and (2) (b) and Article 47(1) and (2) GDPR. For the avoidance of doubt, the Autoriteit Persoonsgegevens recalls that the approval of BCRs does not entail the approval of specific transfers of personal data to be carried out on the basis of the BCRs. Accordingly, the approval of BCRs may not be construed as the approval of transfers to third countries included in the BCRs for which, an essentially equivalent level of protection to that guaranteed within the EU cannot be ensured.
2. The approved BCRs will not require any specific authorization from the concerned SAs.
3. In accordance with Article 58(2)(j) GDPR, each concerned SA maintains the power to order the suspension of data flows to a recipient in a third country or to an international organisation whenever the appropriate safeguards envisaged by the Processor BCRs of **Illumina** are not respected.
4. **Annex 1** forms an integral part of this decision and shall be considered a binding appendix thereto.



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5. **Annex 2** contains the Processor BCRs which are approved by this decision, and forms an integral part of this decision.

The Hague,

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Yours sincerely,

Autoriteit Persoonsgegevens

Chair

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Legal remedy

If you do not agree with this decision, you can submit a notice of objection.³ The notice of objection must be signed and dated, include the name and address of the person submitting it and should entail a description of the decision against which the objection is being lodged and the grounds on which it is based. You must do this within six weeks after this decision is taken by addressing it to the Autoriteit Persoonsgegevens and submitting the notice via PO Box 93374, 2509 AJ The Hague, The Netherlands.⁴

It is also possible to submit a notice of objection via our web form on the website, see <https://www.autoriteitpersoonsgegevens.nl/over-de-autoriteit-persoonsgegevens/bezwaar-maken>.

Please note that submitting a notice of objection does not automatically suspend the effect of this decision.

³ The Dutch General Administrative Act ('Algemene wet bestuursrecht') applies to this procedure.

⁴ Article 6:7 in conjunction with article 6:8 (1) of the Dutch General Administrative Act.



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ANNEX 1 TO THE DECISION

The Processor BCRs of **Illumina** that are hereby approved cover the following:

a. Scope.

Only members of **Illumina** acting as **Processors**, that are legally bound by the BCRs:

Part 1, section 5 of the BCRs

This Policy puts into practice in a legally binding manner the approach taken by Illumina to the protection and management of Customer Personal Data by Illumina when such Customer Personal Data is transferred by Customers to Illumina and Processed by and/or transferred from Exporting Entities to Importing Entities, including any subsequent onward transfers, in all cases where an Illumina Company act as Processor and/or sub-processor in the course of the provision of its services to Customers.

b. EEA countries from which transfers are to be made:

Austria, Belgium, Denmark, Finland, France, Germany, Ireland, Italy, the Netherlands, Norway, Spain, and Sweden.

c. Third countries to which transfers are to be made:

Australia, Brazil, Canada, China, Colombia, India, Israel, Japan, Mexico, New Zealand, Singapore, South Korea, Switzerland, Taiwan, Turkey, United Arab Emirates, United Kingdom, and the USA.

d. Purposes of the transfer:

The Purposes are mentioned in Appendix 2 to the BCRs:

- *Cloud Services data: To provide cloud services to Customers, including genotyping, and sequencing, and analysis services.*
- *Technical support data: To provide technical support and maintenance services to Customers who use Illumina's products and services.*

e. Categories of data subjects concerned by the transfer:

The categories of data subjects concerned by the transfer are mentioned in Appendix 2 to the BCRs:

- **Cloud services**
The categories of Data Subjects whose Personal Data will be Processed by Illumina in the context of the provision of cloud services include patients, research cohorts,



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and other individuals who have consented to the Customer's use of Illumina cloud services, or for whom the Customer has another lawful basis to Process their Personal Data. Illumina's Customer (i.e., a healthcare provider, healthcare institution, etc.) is the Controller.

- **Technical support**

The categories of Data Subjects whose Personal Data will be Processed by Illumina in the context of the provision of technical support and maintenance services include patients, research cohorts, and other individuals who have consented to the Customer's use of Illumina products/services, or for whom the Customer has another lawful basis to Process their Personal Data. Illumina's Customer (i.e., a healthcare provider, healthcare institution, etc.) is the Controller.

f. **Categories of personal data transferred:**

The categories of personal data transferred are mentioned in Appendix 2 to the BCRs:

- **Cloud services data**

When providing cloud services (e.g., to perform computational analysis), Illumina may need to access genomic data and/or pseudonymized information. Where the Customer uses cloud services for the storage of data, including Personal Data (e.g., health related information), Illumina's Processing of the data uploaded by the Customer is limited to the storage of such data and Illumina does not access or otherwise Process such information for any other purposes (including for technical support and maintenance services).

- **Technical Support data**

Illumina will attempt to provide technical support and maintenance services by using run metric data (which is not considered Personal Data). Depending on the issue, Illumina may need to access genomic data and/or pseudonymized information in order to properly troubleshoot and suitably investigate an issue which may arise with respect to the Customer's purchased products/services. Illumina also Processes data localization requirements, i.e., whether data is determined to be sensitive within a region and required to remain within that region or be scrubbed of the sensitive information before transiting outside the region.



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ANNEX 2 TO THE DECISION

Copy of the Processor BCRs of **Illumina**.