Daysoft Limited
Livingstone Boulevard
Glasgow, G72 0BP
UK

10/05/2023

Confirmation Letter Reference: CLNB1639 GBPC200910

To whom it may concern,

Confirmation of receipt of a formal application and conclusion of written agreement 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

This letter confirms that, SGS Belgium NV, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1639 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Daysoft Limited
Livingstone Boulevard
Glasgow, G72 0BP
UK
SRN Number (if available): GB-MF-000006737

Advena Limited.
Tower Business Centre, 2nd Flr;
Tower Street,
Swatar, BKR 4013
Malta
SRN: MT-AR-000000234

The devices covered by the formal application and the written agreement mentioned above are shown at the end of this letter.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired prior to the publication of the Regulation EU 2023/607 on 15 March 2023, this letter also confirms that:

- the manufacturer submitted the MDR application and signed the written agreement by the date of MDD/AIMDD certificate expiry;
- the certificates expired after 26 May 2021 by course of time and were valid at the date of their expiry neither having been suspended nor withdrawn.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3 of MDR (as amended by EU 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body SGS Belgium NV 1639,

Pp Sean Kelly

Virginie SILORET
Global Medical Device Certification Manager
Email: Virginie.siloret@sgs.com
Phone : +41 22 739 98 58

Devices covered by this letter:

Device name / Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Sterile cast moulded one-day disposable hydrogel contact lenses Daysoft Classic 58% and Daysoft SILK 58%. **UDI-DI** 50564212DS58FX	Class IIa	N/A	GB19/964441; NB1639

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023/05/10	Version 1	Initial issue

EC Certificate Production Quality Assurance System: Certificate GB00/51546

The management system of

Daysoft Limited

5 Livingstone Boulevard, Hamilton International Technology Park,
Blantyre, G72 0BP, UK

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex V

For the following products

Sterile cast moulded one-day disposable hydrogel contact lenses
Daysoft Classic 58% and Daysoft SILK 58%.

Where the above scope includes class IIb or class III medical device(s), a valid EC Type Examination Certificate according to Annex III is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 20 March 2018 until 27 February 2023
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 27 February 2021
Issue 14. Certified since 04 May 2000

Certification is based on reports numbered GB/PC 200910

Authorised by

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SGS CE 14 0215