Part 4 – Conditions for the Use of Class 3B and Class 4 Lasers and Intense Light Systems

In these conditions:

Authorised User	Means any person who is suitably qualified to use Class 3B and Class 4 Lasers and/or Intense Light Systems at the Premises
The Controlled Area	Means the room in which a specified piece of the Prescribed Equipment is used
Duty Holder	Means the legal duty holder for the purposes of the Nottinghamshire County Council Act 1985 and health and safety legislation
Expert Registered Healthcare Professional (ERHP)	The ERHP is an expert doctor, dentist, clinical scientist or registered nurse with verifiable clinical expertise in using laser/IPLs to treat patients/clients and who can demonstrate that they have the necessary knowledge and experience to produce a treatment protocol. The ERHP must also be registered with their appropriate professional body and must ensure that any protocols written are within their area of expertise
Intense Light System (ILS)	Means an intense light, being broadband non-coherent light which may or may not be filtered to produce a specified range of wavelengths; such radiation being delivered to the body with the aim of causing thermal, mechanical or chemical damage or physiological changes to structures such as the hair follicles, skin blemishes, or blood vessels while sparing surrounding tissues as far as is reasonably practicable
Laser	Means a Class 3B or Class 4 laser product, as defined in part 1 of the BS EN 60825-1 (Safety of laser products – Equipment classification and requirements)
Laser Protection Advisor (LPA)	Means any person holding a current Certificate of Competence from a recognised assessing body to act as a Laser Protection Adviser or Radiation Protection Adviser e.g. a member of the RPA 2000 or Association of Laser Safety Professionals (ALSP). The LPA is the person providing expert advice on laser/IPL safety. The LPA will be knowledgeable and have expertise in matters relating to optical radiation

	equipment safety. The duties of the LPA include undertaking hazard analysis and risk assessment for each laser and IPL installation which are accepted by the employer to form part of the service's overall risk assessment framework. The LPA advises on laser/IPL safety training, the suitability of personal protective eyewear and ensuring that Local Rules are produced, signed, dated and implemented for each installation.
Laser Protection Supervisor (LPS)	Means a person having undergone the laser safety Core of Knowledge as defined by the Medicines and Healthcare Products Regulatory Agency and who is employed at the Premises to ensure that the Local Rules, risk assessments, operating practices, policies and procedures are implemented
The Local Rules	Means the Risk Assessments and Operating Practices prepared in accordance with condition 3 below
The Premises	Means the premises identified in the body of this licence as the place in which the Prescribed Equipment is operated
The Prescribed Equipment	Means the Laser/Intense Light System(s) identified in the body of this licence, as stipulated in the Premises Licence. The equipment must be legitimately CE-marked to indicate conformity with the relevant European Directive(s)
Specified Treatments	Means the treatments identified in the body of this Licence which are permitted to be carried out in the Premises using the Prescribed Equipment
The Treatment Protocol	Means a protocol produced or approved by an Expert Registered Healthcare Professional (ERHP) in relation to the practitioner's relevant area of practice which includes the matters specified in Condition 2.2 below

1. USE OF LASERS AND INTENSE PULSED LIGHT SYSTEMS

1.1. Only the Specified Treatments may be provided at the Premises and only the Prescribed Equipment may be used to provide those Treatments.

1.2. No person shall be permitted to use the Prescribed Equipment unless they are appropriately trained in accordance with Section 7 and listed on the Register of Authorised Users in accordance with Section 4.

1.3. This Licence shall be displayed in a prominent position within the Premises where it can be easily viewed by Clients.

1.4. Written confirmation shall be provided by the Client prior to treatment that the risks and complications associated with the treatment which they are about to receive have been explained to them and have been understood by them, and that they consent to the treatment.

1.5. No persons under the age of eighteen (18) years may receive Specified Treatment(s) unless for the purpose of medical treatment provided under the supervision or direction of a registered medical practitioner.

2. TREATMENT PROTOCOL

2.1. A Treatment Protocol shall be produced by an Expert Registered Healthcare Professional (ERHP) and submitted to the Council for each treatment, specific to the Prescribed Equipment used, before that treatment is carried out or the equipment is used. If any revisions or amendments are made to the Treatment Protocol during the term of the licence, a copy of the revised Protocol shall be submitted to the Council as soon as is reasonably practicable and in any event within seven working days of those revisions taking effect.

2.2. A Treatment Protocol shall include the following:

2.2.1. name and technical specifications of the equipment to which the Protocol relates

2.2.2. contraindications to treatment

2.2.3. treatment technique – general

2.2.4. the treatment technique specific to application

2.2.5. the risks and complications to be explained to the Client prior to treatment

2.2.6. cleanliness and infection control

2.2.7. pre-treatment tests

2.2.8. post-treatment care

2.2.9. recognition of treatment-related problems

2.2.10. emergency procedures

2.2.11. permitted variation on machine variables

2.2.12. procedure in the event of equipment failure

2.2.13. a version number or date

2.3. The treatment protocol shall be signed by the Expert Registered Healthcare Professional (ERHP) to confirm that the document is fit for purpose.

2.4. The Treatment Protocol shall be followed at all times this licence is in force and the equipment remains Prescribed Equipment.

3. LOCAL RULES

3.1. Local Rules shall be produced and submitted to the Council for the Prescribed Equipment and if applicable for each handpiece on multi-platform laser/ILS to be used at the Premises before that equipment is used. If any revisions or amendments are made to the Local Rules during the term of the licence, a copy of the revised Local Rules shall be submitted to the Council as soon as is reasonably practicable and in any event within seven working days of those revisions taking effect.

3.2. The Licence Holder shall employ the services of a certified LPA to assist in the production of the Local Rules. Evidence of the LPA's laser/IPL certification should be available for reference on site.

3.3. The Local Rules document shall be issued, signed and dated by both the LPA and the duty holder.

3.4. The LPA shall visit the Premises in person initially to produce the Local Rules, risk assessments and operating practices. The risk assessment shall be signed, dated and include a date for next review/assessment.

3.5. A laser/IPL safety audit shall be completed every year and an on-site visit at least every four years by the LPA.

3.6. The Prescribed Equipment shall only be used in accordance with the Local Rules.

3.7. The Local Rules shall include information on the following:

3.7.1. An assessment of the risks associated with the use of the Prescribed Equipment

3.7.2. Device description (including output, serial numbers etc) for all Prescribed Equipment

3.7.3. Written procedures for safe use of the Prescribed Equipment (to include information on prevention of use by unauthorised persons; safe operation of device etc)

3.7.4. Adverse incident procedures including actions that shall be taken in cases of emergency e.g. eye exposure and details of the local accident and emergency department

3.7.5. Emergency shutdown procedures (as set down in manufacturer's instruction manual or treatment protocol)

3.7.6. Details of the nominated LPA (including his or her name, business address and telephone number)

3.7.7. Details of nominated the LPS (including his or her full name, business address and telephone number)

3.7.8. Training requirements for Authorised Users for the use of Prescribed Equipment

3.7.9. A detailed plan of the Controlled Area(s), showing each piece of the Prescribed Equipment to be used in the Area and details of access to the Equipment, together with a complete plan of the Premises

3.7.10. Responsibilities of Authorised Users

3.7.11. Details of Protective eyewear (including information relating to when eyewear be worn and the minimum specification of protection required)

3.8. The Local Rules shall be updated if there are any changes made to any of the items detailed in Condition 3.7 above. Each update shall be approved by the LPA.

3.9. The Local Rules relevant to each specific piece of Prescribed Equipment shall be kept in the Controlled Area relating to that piece of Equipment whilst it is being operated.

4. REGISTER OF AUTHORISED USERS

4.1. A Register of Authorised Users shall be kept at the Establishment which includes details of trained personnel and signed declarations by those individuals stating that they accept and understand the procedures drawn up for the use of Prescribed Equipment.

4.2. Copies of any training or qualification certificates held by the Authorised Users shall be kept with the Register of Authorised Users.

4.3. Authorised Users shall sign statements to the effect that they have read, understood and will follow Local Rules at all times.

5. REGISTER OF LASER USE

5.1. A register shall be maintained for each piece of Prescribed Equipment to record the following information each time that the equipment is operated:

5.1.1. the full name, date of birth and address of the person treated or a unique link to the customer details kept elsewhere

5.1.2. date and time of treatment

5.1.3. the Authorised User's signature

5.1.4. the treatment given, including the site and an indication of the size of the area treated, type of treatment; equipment used and Laser/ILS parameters used

5.1.5. any accident or adverse effects

5.2. The Register shall be either:

a. A bound hard copy book with sequentially numbered pages with the front page containing details of the name and serial number of Prescribed Equipment, or;

b. An electronic record that does not allow overwriting to the original entry

6. LASER PROTECTION SUPERVISOR (LPS)

6.1. A suitably qualified and authorised member of staff having day to day responsibility for the premises shall be identified as the Laser Protection Supervisor (LPS), who shall ensure that the Register is maintained and the Local Rules and licence conditions are adhered to.

7. TRAINING

7.1. All Authorised Users shall hold the Core of Knowledge Training Certificate. Core of knowledge training shall be repeated periodically at least every 5 years.

7.2. Authorised Users shall only use the Prescribed Equipment for treatments for which they have received the appropriate training; including suitable and sufficient training provided by the manufacturer or supplier for each specific piece of Prescribed Equipment and if applicable each handpiece that they operate on a multi-platform laser/ILS.

7.3. All Authorised Users shall receive regular update training, both planned and in reaction to relevant technological and medical developments.

7.4. Details of all training shall be recorded in the Register of Authorised Users required by Condition 4.1 above.

8. CONTROLLED AREA

8.1. Prescribed Equipment shall only be used in a Controlled Area designated for its use in accordance with Condition 3.7.9 above.

8.2. The Controlled Area shall be clearly defined and not used for any other purposes, or as access or egress to other areas when treatment is being carried out.

8.3. An approved warning sign or light entry system which complies with current British Standards shall be in place on the door of the Controlled Area which shall only be on display when the Prescribed Equipment is in use.

8.4. The door to the Controlled Area shall be fitted with a suitable locking device to control access, which can be operated from the outside in an emergency.

8.5. Any windows in the Controlled Area shall be fitted with opaque blinds approved by the LPA, unless otherwise agreed in writing by the Local Authority.

8.6. The Controlled Area shall be kept clear of clutter.

8.7. Surfaces within the Controlled Area shall be of a matt or eggshell finish wherever possible. Mirrors and/or other reflective surfaces shall be covered or removed during treatment, and jewellery shall not be worn by the Authorised User or Client.

8.8. All Prescribed Equipment shall comply with current and any superseding standards (BS EN 60601-2-22; and BS EN 60601-2-57 for ILS) and shall display labels identifying them, their wavelength or range of wavelengths and the maximum output fluence, energy or power of the radiation emitted. The labels shall be clearly visible on the Prescribed Equipment.

8.9. Lasers/ILS shall be serviced annually or in accordance with the Manufacturers' Instructions, by a competent person. A record of all such servicing, and any repairs to the Laser/ILS equipment shall be kept at the Premises.

8.10. The LPS shall ensure that the key or access code to any Prescribed Equipment is kept secure and only Authorised Users have access to the key or access code.

8.11. No more than one Prescribed Equipment shall be switched on in the Controlled Area during Client treatment.

8.12. When the Prescribed Equipment is in stand-by mode or in operation, the number of persons in the room shall be kept to a minimum.

9. PROTECTIVE EYEWEAR

9.1. Protective eyewear which has been approved in writing by the LPA shall be worn by everyone within the Controlled Area whenever there is a risk of exposure to the laser beam/intense light radiation.

9.2. All protective eyewear shall be clearly marked with the wavelength range and protection offered as detailed in the Local Rules and shall comply with BS EN 207:2009 for lasers and BS ISO 12609-1 and -2:2013 for ILS, as amended.

9.3. Protective eyewear shall be maintained in a clean serviceable condition. Suitable storage shall be provided for protective eyewear, to prevent damage

and unauthorised access to the equipment. Eyewear shall be cleaned as per the manufacturer's instructions.

10. INSPECTION OF RECORDS

10.1. All records, training attendance certificates, and documents to which these conditions refer shall be kept on the Premises and shall be available for inspection by an Officer authorised by the Local Authority upon request.